

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
30 November 2000 (30.11.2000)

PCT

(10) International Publication Number
WO 00/71043 A1

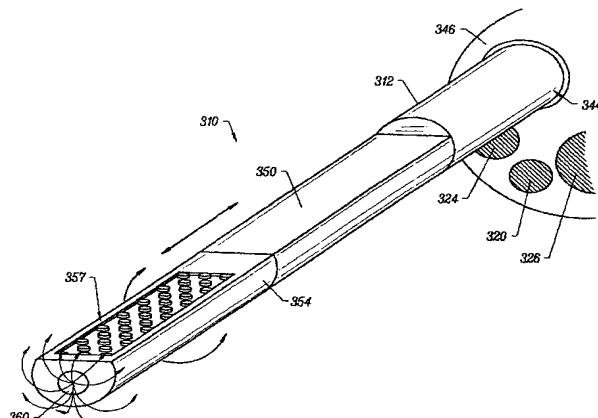
- (51) International Patent Classification⁷: **A61B 18/14**
- (21) International Application Number: PCT/US00/13706
- (22) International Filing Date: 17 May 2000 (17.05.2000)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:
09/316,472 21 May 1999 (21.05.1999) US
60/204,206 12 May 2000 (12.05.2000) US
- (71) Applicant: ARTHROCARE CORPORATION [US/US]; 595 North Pastoria Avenue, Sunnyvale, CA 94086 (US).
- (72) Inventors: HOVDA, David, C.; 1900 Miramonte Avenue, Mountain View, CA 94040 (US). ELLSBERRY, Maria, B.; 43671 Skye Road, Fremont, CA 94539 (US). THAPLIYAL, Hira, V.; 1192 Volti Lane, Los Altos, CA 94024 (US). EGGERS, Philip, E.; 5366 Reserve Drive, Dublin, OH 43017 (US).
- (74) Agent: RAFFLE, John, T.; ArthroCare Corporation, 595 North Pastoria Avenue, Sunnyvale, CA 94086 (US).
- (81) Designated States (national): AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:

— With international search report.

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEMS AND METHODS FOR ELECTROSURGICAL TREATMENT OF INTERVERTEBRAL DISCS



WO 00/71043 A1

(57) Abstract: This invention is systems, apparatus, methods for ablation, resection, aspiration, collagen shrinkage, hemostasis of tissue, other body structures in open, and endoscopic spine surgery. In particular, the present invention includes a channeling technique in which small holes or channels are formed within spinal discs, and thermal energy is applied to the tissue surface immediately surrounding these holes or channels to cause thermal damage to the tissue surface, thereby stiffening the surrounding tissue structure for reducing the volume of the disc to relieve pressure on the surrounding nerves. High frequency voltage is applied between one or more active electrode(362), and one or more return electrode (360) to volumetrically remove or ablate at least a portion of the disc tissue. The active electrodes are advanced through the space left by the ablated tissue to form a channel, hole, divot, or other space in the disc tissue. In addition, the high frequency voltage effects a controlled depth of thermal heating of the tissue surrounding the hole to de-bulk, and/or stiffen the disc structure, thereby relieving neck or back pain.

5 **SYSTEMS AND METHODS FOR ELECTROSURGICAL
TREATMENT OF INTERVERTEBRAL DISCS**

RELATED APPLICATIONS

The present invention is a continuation-in-part of U.S. Patent Application No. 09/295,687, filed April 21, 1999 (Attorney Docket No. E-7-2) and U.S. Patent Application Nos. 09/054,323 and 09/268,616, filed April 2, 1998 and March 15, 1999, respectively (Attorney Docket Nos. E-5 and E-7-1, respectively), each of which are continuation-in-parts of Serial No. 08/990,374, filed December 15, 1997 (Attorney Docket E-3), which is a continuation-in-part of U.S. Patent Application No. 08/485,219, filed on June 7, 1995 (Attorney Docket 16238-000600), the complete disclosures of which are incorporated herein by reference for all purposes. This application is also a continuation-in-part of U.S. Patent Application No. 09/026,851, filed February 20, 1999 (Attorney Docket No. S-2), which is a continuation-in-part of U.S. Patent Application No. 08/690,159, filed July 18, 1996 (Attorney Docket No. 16238-001610), the complete disclosure of which is incorporated herein by reference for all purposes.

20 The present invention is related to commonly assigned co-pending U.S. Patent Application No. 09/181,926, filed October 28, 1998 (Attorney Docket No. S-1-2), U.S. Patent Application No. 09/130,804, filed August 7, 1998 (Attorney Docket No. S-4), U.S. Patent Application No. 09/058,571, filed on April 10, 1998 (Attorney Docket No. CB-2), U.S. Patent Application No. 09/248,763, filed February 12, 1999 (Attorney Docket No. CB-7), U.S. Patent Application No. 09/026,698, filed February 20, 1998 (Attorney Docket No. S-3), U.S. Patent Application No. 09/074,020, filed on May 6, 1998 (Attorney Docket No. E-6), U.S. Patent Application No. 09/010,382, filed January 21, 1998 (Attorney Docket A-6), U.S. Patent Application No. 09/032,375, filed February 27, 1998 (Attorney Docket No. CB-3), U.S. Patent Application Nos. 08/977,845, filed on November 25, 1997 (Attorney Docket No. D-2), 08/942,580, filed on October 2, 1997 (Attorney Docket No. 16238-001300), U.S. Application No. 08/753,227, filed on November 22, 1996 (Docket 16238-002200), U.S. Application No. 08/687792, filed on July 18, 1996 (Docket No. 16238-001600), and PCT International Application, U.S. National Phase Serial No. PCT/US94/05168, filed on May 10, 1994, now U.S. Patent No.

5,697,909 (Attorney Docket 16238-000440), which was a continuation-in-part of U.S. Patent Application No. 08/059,681, filed on May 10, 1993 (Attorney Docket 16238-000420), which was a continuation-in-part of U.S. Patent Application No. 07/958,977, filed on October 9, 1992 (Attorney Docket 16238-000410) which was a continuation-in-
5 part of U.S. Patent Application No. 07/817,575, filed on January 7, 1992 (Attorney Docket 16238-00040), the complete disclosures of which are incorporated herein by reference for all purposes. The present invention is also related to commonly assigned U.S. Patent No. 5,697,882, filed November 22, 1995 (Attorney Docket 16238-000700), the complete disclosure of which is incorporated herein by reference for all purposes.

10

BACKGROUND OF THE INVENTION

The present invention relates generally to the field of electrosurgery, and more particularly to surgical devices and methods which employ high frequency electrical
15 energy to treat tissue in regions of the spine. The present invention is particularly suited for the treatment of herniated discs.

The major causes of persistent, often disabling, back pain are disruption of the disc annulus, chronic inflammation of the disc (e.g., herniation), or relative instability of the vertebral bodies surrounding a given disc, such as the instability that often occurs
20 due to a degenerative disease. Intervertebral discs mainly function to cushion and tether the vertebrae, providing flexibility and stability to the patient's spine. Spinal discs comprise a central hydrostatic cushion, the nucleus pulposus, surrounded by a multi-layered fibrous ligament, the annulus fibrosis. As discs degenerate, they lose their water content and height, bringing the adjoining vertebrae closer together. This results in a
25 weakening of the shock absorption properties of the disc and a narrowing of the nerve openings in the sides of the spine which may pinch these nerves. This disc degeneration can eventually cause back and leg pain. Weakness in the annulus from degenerative discs or disc injury can allow fragments of nucleus pulposis from within the disc space to migrate into the spinal canal. There, displaced nucleus or protrusion of annulus fibrosis,
30 e.g., herniation, may impinge on spinal nerves. The mere proximity of the nucleus pulposis or a damaged annulus to a nerve can cause direct pressure against the nerve, resulting in numbness and weakness of leg muscles.

Often, inflammation from disc herniation can be treated successfully by non-surgical means, such as rest, therapeutic exercise, oral anti-inflammatory medications or epidural injection of corticosteroids. In some cases, the disc tissue is irreparably damaged, thereby necessitating removal of a portion of the disc or the entire disc to eliminate the 5 source of inflammation and pressure. In more severe cases, the adjacent vertebral bodies must be stabilized following excision of the disc material to avoid recurrence of the disabling back pain. One approach to stabilizing the vertebrae, termed spinal fusion, is to insert an interbody graft or implant into the space vacated by the degenerative disc. In this procedure, a small amount of bone may be grafted from other portions of the body, such as 10 the hip, and packed into the implants. This allows the bone to grow through and around the implant, fusing the vertebral bodies and alleviating the pain.

Until recently, spinal discectomy and fusion procedures resulted in major operations and traumatic dissection of muscle and bone removal or bone fusion. To overcome the disadvantages of traditional traumatic spine surgery, minimally invasive 15 spine surgery was developed. In endoscopic spinal procedures, the spinal canal is not violated and therefore epidural bleeding with ensuing scarring is minimized or completely avoided. In addition, the risk of instability from ligament and bone removal is generally lower in endoscopic procedures than with open discectomy. Further, more rapid rehabilitation facilitates faster recovery and return to work.

Minimally invasive techniques for the treatment of spinal diseases or 20 disorders include chemonucleolysis, laser techniques and mechanical techniques. These procedures generally require the surgeon to form a passage or operating corridor from the external surface of the patient to the spinal disc(s) for passage of surgical instruments, implants and the like. Typically, the formation of this operating corridor requires the 25 removal of soft tissue, muscle or other types of tissue depending on the procedure (i.e., laparascopic, thoracoscopic, arthroscopic, back, etc.). This tissue is usually removed with mechanical instruments, such as pituitary rongeurs, curettes, graspers, cutters, drills, microdebriders and the like. Unfortunately, these mechanical instruments greatly lengthen and increase the complexity of the procedure. In addition, these instruments sever blood 30 vessels within this tissue, usually causing profuse bleeding that obstructs the surgeon's view of the target site.

Once the operating corridor is established, the nerve root is retracted and a portion or all of the disc is removed with mechanical instruments, such as a pituitary

rongeur. In addition to the above problems with mechanical instruments, there are serious concerns because these instruments are not precise, and it is often difficult, during the procedure, to differentiate between the target disc tissue, and other structures within the spine, such as bone, cartilage, ligaments, nerves and non-target tissue. Thus, the surgeon 5 must be extremely careful to minimize damage to the cartilage and bone within the spine, and to avoid damaging nerves, such as the spinal nerves and the dura mater surrounding the spinal cord.

Lasers were initially considered ideal for spine surgery because lasers ablate or vaporize tissue with heat, which also acts to cauterize and seal the small blood vessels in 10 the tissue. Unfortunately, lasers are both expensive and somewhat tedious to use in these procedures. Another disadvantage with lasers is the difficulty in judging the depth of tissue ablation. Since the surgeon generally points and shoots the laser without contacting the tissue, he or she does not receive any tactile feedback to judge how deeply the laser is cutting. Because healthy tissue, bones, ligaments and spinal nerves often lie within close 15 proximity of the spinal disc, it is essential to maintain a minimum depth of tissue damage, which cannot always be ensured with a laser.

Monopolar radiofrequency devices have been used in limited roles in spine surgery, such as to cauterize severed vessels to improve visualization. These monopolar devices, however, suffer from the disadvantage that the electric current will flow through 20 undefined paths in the patient's body, thereby increasing the risk of unwanted electrical stimulation to portions of the patient's body. In addition, since the defined path through the patient's body has a relatively high impedance (because of the large distance or resistivity of the patient's body), large voltage differences must typically be applied between the return and active electrodes in order to generate a current suitable for ablation 25 or cutting of the target tissue. This current, however, may inadvertently flow along body paths having less impedance than the defined electrical path, which will substantially increase the current flowing through these paths, possibly causing damage to or destroying surrounding tissue or neighboring peripheral nerves.

Other disadvantages of conventional RF devices, particularly monopolar 30 devices, is nerve stimulation and interference with nerve monitoring equipment in the operating room. In addition, these devices typically operate by creating a voltage difference between the active electrode and the target tissue, causing an electrical arc to form across the physical gap between the electrode and tissue. At the point of contact of

the electric arcs with tissue, rapid tissue heating occurs due to high current density between the electrode and tissue. This high current density causes cellular fluids to rapidly vaporize into steam, thereby producing a "cutting effect" along the pathway of localized tissue heating. Thus, the tissue is parted along the pathway of evaporated cellular fluid, 5 inducing undesirable collateral tissue damage in regions surrounding the target tissue site. This collateral tissue damage often causes indiscriminate destruction of tissue, resulting in the loss of the proper function of the tissue. In addition, the device does not remove any tissue directly, but rather depends on destroying a zone of tissue and allowing the body to eventually remove the destroyed tissue.

10

SUMMARY OF THE INVENTION

The present invention provides systems, apparatus and methods for 15 selectively applying electrical energy to structures within a patient's body, such as tissue within or around the spine. The systems and methods of the present invention are useful for ablation, resection, aspiration, collagen shrinkage and/or hemostasis of tissue and other body structures in open and endoscopic spine surgery. In particular, the present invention includes a channeling technique in which small holes or channels are formed within 20 intervertebral discs, and thermal energy is applied to the tissue surface immediately surrounding these holes or channels to cause thermal damage to the tissue surface, thereby stiffening the surrounding tissue structure and for reducing the volume of the disc to relieve pressure on the surrounding nerves.

Methods of the present invention include introducing one or more active 25 electrode(s) into the patient's spine and positioning the active electrode(s) adjacent the target tissue, e.g., a disc. High frequency voltage is applied between the active electrode(s) and one or more return electrode(s) to volumetrically remove or ablate at least a portion of the target tissue, and the active electrode(s) are advanced through the space left by the ablated tissue to form a channel, hole, divot or other space in the disc tissue. 30 The active electrode(s) are then removed from the channel, and other channels or holes may be formed at suitable locations in the disc. In preferred embodiments, high frequency voltage is applied to the active electrode(s) as they are removed from the hole or channel. The high frequency voltage is below the threshold for ablation of tissue to effect

hemostasis of severed blood vessels within the tissue surface surrounding the hole. In addition, the high frequency voltage effects a controlled depth of thermal heating of the tissue surrounding the hole to thermally damage or create a lesion within the tissue surrounding the hole to debulk and/or stiffen the disc structure, thereby relieving neck or back pain.

In a specific configuration, electrically conductive media, such as isotonic saline or an electrically conductive gel, is delivered to the target site within the spine to substantially surround the active electrode(s) with the conductive media. The conductive media may be delivered through an instrument to the specific target site, or the entire target region may be filled with conductive media such that the electrode terminal(s) are submerged during the procedure. Alternatively, the distal end of the instrument may be dipped or otherwise applied to the conductive media prior to introduction into the patient's body. In all of these embodiments, the electrically conductive media is applied or delivered such that it provides a current flow path between the active and return electrode(s). In other embodiments, the intracellular conductive fluid in the patient's tissue may be used as a substitute for, or as a supplement to, the electrically conductive media that is applied or delivered to the target site. For example, in some embodiments, the instrument is dipped into conductive media to provide a sufficient amount of fluid to initiate the requisite conditions for ablation. After initiation, the conductive fluid already present in the patient's tissue is used to sustain these conditions.

In an exemplary embodiment, the active electrode(s) are advanced into the target disc tissue in the ablation mode, where the high frequency voltage is sufficient to ablate or remove the target tissue through molecular dissociation or disintegration processes. In these embodiments, the high frequency voltage applied to the active electrode(s) is sufficient to vaporize an electrically conductive fluid (e.g., gel, saline and/or intracellular fluid) between the active electrode(s) and the tissue. Within the vaporized fluid, a ionized plasma is formed and charged particles (e.g., electrons) are accelerated towards the tissue to cause the molecular breakdown or disintegration of several cell layers of the tissue. This molecular dissociation is accompanied by the volumetric removal of the tissue. The short range of the accelerated charged particles within the plasma layer confines the molecular dissociation process to the surface layer to minimize damage and necrosis to the underlying tissue. This process can be precisely controlled to effect the volumetric removal of tissue as thin as 10 to 150 microns with

minimal heating of, or damage to, surrounding or underlying tissue structures. A more complete description of this phenomena is described in commonly assigned U.S. Patent No. 5,697,882 the complete disclosure of which is incorporated herein by reference.

The active electrode(s) are usually removed from the holes or channels in
5 the subablation or thermal heating mode, where the high frequency voltage is below the threshold for ablation as described above, but sufficient to coagulate severed blood vessels and to effect thermal damage to at least the surface tissue surrounding the holes. In some embodiments, the active electrode(s) are immediately removed from the holes after being placed into the subablation mode. In other embodiments, the physician may desire to
10 control the rate of removal of the active electrode(s) and/or leave the active electrode(s) in the hole for a period of time, e.g., on the order of about 5 to 30 seconds, in the subablation mode to increase the depth of thermal damage to the disc tissue.

In one method, high frequency voltage is applied, in the ablation mode, between one or more active electrode(s) and a return electrode spaced axially from the
15 active electrode(s), and the active electrode(s) are advanced into the tissue to form a hole or channel as described above. High frequency voltage is then applied between the return electrode and one or more third electrode(s), in the thermal heating mode, as the electrosurgical instrument is removed from the hole. In one embodiment, the third electrode is a dispersive return pad on the external surface of the skin. In this
20 embodiment, the thermal heating mode is a monopolar mode, in which current flows from the return electrode, through the patient's body, to the return pad. In other embodiments, the third electrode(s) are located on the electrosurgical instrument and the thermal heating mode is bipolar. In all of the embodiments, the third electrode(s) are designed to increase the depth of current penetration in the tissue over the ablation mode so as to increase the
25 thermal damage applied to the disc.

In another method, the third or coagulation electrode is placed in the thermal heating mode at the same time that the active electrode(s) is placed in the ablation mode. In this embodiment, electric current is passed from the coagulation electrode, through the tissue surrounding the hole, to the return electrode at the same time that
30 current is passing between the active and return electrodes. In a specific configuration, this is accomplished by reducing the voltage applied to the coagulation electrode with a passive or active voltage reduction element coupled between the power supply and the coagulation electrode. In this manner, when the coagulation electrode is advanced into the

tissue, the electric circuit between the coagulation and return electrodes is closed by the tissue surrounding the hole, and thus immediately begins to heat and coagulate this tissue.

In another method, an electrosurgical instrument having an electrode assembly is dipped into electrically conductive fluid such that the conductive fluid is located around and between both active and return electrodes in the electrode assembly. The instrument is then introduced into the patient's spine either percutaneously or through an open procedure, and a plurality of holes are formed within the disc as described above.

The instrument is removed from each hole in the thermal heating mode to create thermal damage and to coagulate blood vessels. Typically, the instrument will be dipped into the conductive fluid after being removed from each hole to ensure that sufficient conductive fluid exists for plasma formation and to conduct electric current between the active and return electrodes. This procedure reduces the volume of the intervertebral disc, which helps to alleviate neck and back pain.

In another aspect of the invention, a method for treating a degenerative intervertebral disc involves positioning one or more active electrode(s) adjacent to selected nerves embedded in the walls of the disc, and positioning one or more return electrode(s) in the vicinity of the active electrode(s) in or on the disc. A sufficient high frequency voltage difference is applied between the active and return electrodes to denervate the selected nerves or to break down enzyme systems and pain generating neurotransmitters in the disc, and thus relieve pain. In some embodiments, the current path between the active and return electrode(s) is generated at least in part by an electrically conductive fluid introduced to the target site. In others, the disc tissue completes this current path.

In another aspect of the invention, a method for treating degenerative intervertebral discs involves positioning one or more active electrode(s) adjacent to or within the nucleus pulposis, and positioning one or more return electrode(s) in the vicinity of the active electrode(s) in or on the disc. A sufficient high frequency voltage difference is applied between the active and return electrodes to reduce water content of the nucleus pulposis and/or shrink the collagen fibers within the nucleus pulposis to tighten the disc. In some embodiments, the current path between the active and return electrode(s) is generated at least in part by an electrically conductive fluid introduced to the target site. In others, the disc tissue completes this current path.

In yet another aspect of the invention, a method for treating degenerative intervertebral discs involves positioning one or more active electrode(s) adjacent to or

within a annular fissure on the inner wall of the annulus fibrosis, and positioning one or more return electrode(s) in the vicinity of the active electrode(s) in or around the disc. A sufficient high frequency voltage difference is applied between the active and return electrodes to weld, seal or shrink the collagen fibers in the annular fissure, thus repairing the fissure. Typically, the voltage is selected to provide sufficient energy to the fissure to raise the tissue temperature to at least about 50°C to 70°C for a sufficient time to cause the collagen fibers to shrink or weld together. In some embodiments, the current path between the active and return electrode(s) is generated at least in part by an electrically conductive fluid introduced to the target site. In others, the disc tissue completes this current path.

Systems according to the present invention generally include an electrosurgical instrument having a shaft with proximal and distal ends, an electrode assembly at the distal end and one or more connectors coupling the electrode assembly to a source of high frequency electrical energy. The instrument will comprise a probe or catheter shaft having a proximal end and a distal end which supports the electrode assembly. The probe or catheter may assume a wide variety of configurations, with the primary purpose being to introduce the electrode assembly to the patient's spine (in an open or endoscopic procedure) and to permit the treating physician to manipulate the electrode assembly from a proximal end of the shaft. The electrode assembly includes one or more active electrode(s) configured for tissue ablation, a return electrode spaced from the active electrode(s) on the instrument shaft and a third, coagulation electrode spaced from the return electrode on the instrument shaft.

The system further includes a power source coupled to the electrodes on the instrument shaft for applying a high frequency voltage between the active and return electrodes, and between the coagulation and return electrodes, at the same time. In one embodiment, the system comprises a voltage reduction element coupled between the power source and the coagulation electrode to reduce the voltage applied to the coagulation electrode. The voltage reduction element will typically comprise a passive element, such as a capacitor, resistor, inductor or the like. In the representative embodiment, the power supply will apply a voltage of about 150 to 600 volts rms between the active and return electrodes, and the voltage reduction element will reduce this voltage to about 20 to 300 volts rms to the coagulation electrode. In this manner, the voltage delivered to the coagulation electrode is below the threshold for ablation of tissue, but high enough to coagulation and heat the tissue.

The active electrode(s) may comprise a single active electrode, or an electrode array, extending from an electrically insulating support member, typically made of an inorganic material such as ceramic, silicone or glass. The active electrode will usually have a smaller exposed surface area than the return and coagulation electrodes such 5 that the current densities are much higher at the active electrode than at the other electrodes. Preferably, the return and coagulation electrodes have relatively large, smooth surfaces extending around the instrument shaft to reduce current densities, thereby minimizing damage to adjacent tissue.

The apparatus may further include a fluid delivery element for delivering 10 electrically conducting fluid to the active electrode(s) and the target site. The fluid delivery element may be located on the instrument, e.g., a fluid lumen or tube, or it may be part of a separate instrument. Alternatively, an electrically conducting gel or spray, such as a saline electrolyte or other conductive gel, may be applied to the electrode assembly or the target site. In this embodiment, the apparatus may not have a fluid 15 delivery element. In both embodiments, the electrically conducting fluid will preferably generate a current flow path between the active electrode(s) and the return electrode(s).

20

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of an electrosurgical system incorporating a power supply and an electrosurgical probe for tissue ablation, resection, incision, contraction and for vessel hemostasis according to the present invention;

25 Fig. 2 schematically illustrates one embodiment of a power supply according to the present invention;

Fig. 3 illustrates an electrosurgical system incorporating a plurality of active electrodes and associated current limiting elements;

30 Fig. 4 is a side view of an electrosurgical probe according to the present invention;

Fig. 5 is a view of the distal end portion of the probe of Fig. 2

Fig. 6 is an exploded view of a proximal portion of the electrosurgical probe;

Figs. 7A and 7B are perspective and end views, respectively, of an alternative electrosurgical probe incorporating an inner fluid lumen;

Figs. 8A-8C are cross-sectional views of the distal portions of three different embodiments of an electrosurgical probe according to the present invention;

5 Figs. 9-13 are end views of alternative embodiments of the probe of Fig. 4, incorporating aspiration electrode(s);

Figs. 14A-14C illustrate an alternative embodiment incorporating a screen electrode;

10 Figs. 15A-15D illustrate four embodiments of electrosurgical probes specifically designed for treating spinal defects;

Fig. 16 illustrates an electrosurgical system incorporating a dispersive return pad for monopolar and/or bipolar operations;

Fig. 17 illustrates a catheter system for electrosurgical treatment of intervertebral discs according to the present invention;

15 Figs. 18-22 illustrate a method of performing a microendoscopic discectomy according to the principles of the present invention;

Figs. 23-25 illustrates another method of treating a spinal disc with one of the catheters or probes of the present invention;

20 Fig. 26 is a schematic view of the proximal portion of another electrosurgical system for endoscopic spine surgery incorporating an electrosurgical instrument according to the present invention;

Fig. 27 is an enlarged view of a distal portion of the electrosurgical instrument of Fig. 26;

25 Fig. 28 illustrates a method of ablating a volume of tissue from the nucleus pulposis of a herniated disc with the electrosurgical system of Fig. 26;

Fig. 29 illustrates a planar ablation probe for ablating tissue in confined spaces within a patient's body according to the present invention;

Fig. 30 illustrates a distal portion of the planar ablation probe of Fig. 19;

30 Fig. 31A is a front sectional view of the planar ablation probe, illustrating an array of semi-cylindrical active electrodes;

Fig. 31B is a front sectional view of an alternative planar ablation probe, illustrating an array of active electrodes having opposite polarities;

Fig. 32 is a top, partial section, view of the working end of the planar ablation probe of Fig. 29;

Fig. 33 is a side cross-sectional view of the working end of the planar ablation probe, illustrating the electrical connection with one of the active electrodes of
5 Fig. 32;

Fig. 34 is a side cross-sectional view of the proximal end of the planar ablation probe, illustrating the electrical connection with a power source connector;

Fig. 35 is a schematic view illustrating the ablation of soft tissue from adjacent surfaces of the vertebrae with the planar ablation probe of the present invention;

10 Fig. 36 is a perspective view of an alternative embodiment of the planar ablation probe incorporating a ceramic support structure with conductive strips printed thereon;

Fig. 37 is a top partial cross-sectional view of the planar ablation probe of
Fig. 29;

15 Fig. 38 is an end view of the probe of Fig. 29;

Fig. 39A illustrates a system having a curved distal tip and an insulator for protecting a dura mater;

Fig. 39B is an end view of one embodiment of the system of Fig. 39A;

20 Fig. 40 illustrates the system of Fig. 39A being percutaneously introduced anteriorly into a target spinal disc;

Fig. 41 illustrates the system of Fig. 39A being percutaneously introduced posteriorly into a target spinal disc;

Fig. 42 is an electrosurgical probe having a fluid delivery lumen and an aspiration lumen;

25 Fig. 43 is an end view of the electrosurgical probe of Fig. 42; and

Fig. 44 illustrates a system having an aspiration lumen and a fluid delivery lumen.

Figs. 45A-45D illustrate four embodiments of electrosurgical probes specifically designed for treating spinal defects;

30 Fig. 46 illustrates an electrosurgical system having a dispersive return pad for monopolar and/or bipolar operations;

Fig. 47 illustrates an electrosurgical probe being inserted into a intervertebral disc; and

Figs 48A and 48B illustrate the distal tip of the electrosurgical probe moving along an inner surface of the annulus fibrosus.

DESCRIPTION OF SPECIFIC EMBODIMENTS

The present invention provides systems and methods for selectively applying electrical energy to a target location within or on a patient's body, particularly including tissue or other body structures in the spine. These procedures include treating degenerative discs, laminectomy/diskectomy procedures for treating herniated discs, decompressive laminectomy for stenosis in the lumbosacral and cervical spine, localized tears or fissures in the annulus, nucleotomy, disc fusion procedures, medial facetectomy, posterior lumbosacral and cervical spine fusions, treatment of scoliosis associated with vertebral disease, foraminotomies to remove the roof of the intervertebral foramina to relieve nerve root compression and anterior cervical and lumbar discectomies. These procedures may be performed through open procedures, or using minimally invasive techniques, such as thoracoscopy, arthroscopy, laparoscopy or the like.

The present invention involves techniques for treating disc abnormalities with RF energy. In some embodiments, RF energy is used to ablate, debulk and/or stiffen the tissue structure of the disc to reduce the volume of the disc, thereby relieving neck and back pain. In one aspect of the invention, spinal disc tissue is volumetrically removed or ablated to form holes, channels, divots or other spaces within the disc. In this procedure, a high frequency voltage difference is applied between one or more active electrode(s) and one or more return electrode(s) to develop high electric field intensities in the vicinity of the target tissue. The high electric field intensities adjacent the active electrode(s) lead to electric field induced molecular breakdown of target tissue through molecular dissociation (rather than thermal evaporation or carbonization). Applicant believes that the tissue structure is volumetrically removed through molecular disintegration of larger organic molecules into smaller molecules and/or atoms, such as hydrogen, oxygen, oxides of carbon, hydrocarbons and nitrogen compounds. This molecular disintegration completely removes the tissue structure, as opposed to dehydrating the tissue material by the removal

of liquid within the cells of the tissue, as is typically the case with electrosurgical desiccation and vaporization.

The high electric field intensities may be generated by applying a high frequency voltage that is sufficient to vaporize an electrically conducting fluid over at least 5 a portion of the active electrode(s) in the region between the distal tip of the active electrode(s) and the target tissue. The electrically conductive fluid may be a liquid or gas, such as isotonic saline, blood or intracellular fluid, delivered to, or already present at, the target site, or a viscous fluid, such as a gel, applied to the target site. Since the vapor layer or vaporized region has a relatively high electrical impedance, it increases the 10 voltage differential between the electrode terminal tip and the tissue and causes ionization within the vapor layer due to the presence of an ionizable species (e.g., sodium when isotonic saline is the electrically conducting fluid). This ionization, under the conditions described herein, induces the discharge of energetic electrons and photons from the vapor layer and to the surface of the target tissue. This energy may be in the form of energetic 15 photons (e.g., ultraviolet radiation), energetic particles (e.g., electrons or ions) or a combination thereof. A more detailed description of this phenomena, termed Coblation® can be found in commonly assigned U.S. Patent No. 5,697,882 the complete disclosure of which is incorporated herein by reference.

Applicant believes that the principle mechanism of tissue removal in the 20 Coblation® mechanism of the present invention is energetic electrons or ions that have been energized in a plasma adjacent to the active electrode(s). When a liquid is heated enough that atoms vaporize off the surface faster than they recondense, a gas is formed. When the gas is heated enough that the atoms collide with each other and knock their electrons off in the process, an ionized gas or plasma is formed (the so-called "fourth state of matter"). A 25 more complete description of plasma can be found in Plasma Physics, by R.J. Goldston and P.H. Rutherford of the Plasma Physics Laboratory of Princeton University (1995). When the density of the vapor layer (or within a bubble formed in the electrically conducting liquid) becomes sufficiently low (i.e., less than approximately 1020 atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently 30 injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Once the ionic particles in the plasma layer have sufficient energy, they accelerate towards the target tissue. Energy evolved by the energetic electrons (e.g., 3.5 eV to 5 eV) can subsequently bombard a molecule and break its bonds,

dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

Plasmas may be formed by heating a gas and ionizing the gas by driving an electric current through it, or by shining radio waves into the gas. Generally, these 5 methods of plasma formation give energy to free electrons in the plasma directly, and then electron-atom collisions liberate more electrons, and the process cascades until the desired degree of ionization is achieved. Often, the electrons carry the electrical current or absorb the radio waves and, therefore, are hotter than the ions. Thus, in applicant's invention, the electrons, which are carried away from the tissue towards the return electrode, carry 10 most of the plasma's heat with them, allowing the ions to break apart the tissue molecules in a substantially non-thermal manner.

In some embodiments, the present invention applies high frequency (RF) electrical energy in an electrically conducting media environment to remove (i.e., resect, cut or ablate) a tissue structure and to seal transected vessels within the region of the target 15 tissue. The present invention may also be useful for sealing larger arterial vessels, e.g., on the order of about 1 mm in diameter. In some embodiments, a high frequency power supply is provided having an ablation mode, wherein a first voltage is applied to an electrode terminal sufficient to effect molecular dissociation or disintegration of the tissue, and a coagulation mode, wherein a second, lower voltage is applied to an electrode 20 terminal (either the same or a different electrode) sufficient to achieve hemostasis of severed vessels within the tissue. In other embodiments, an electrosurgical instrument is provided having one or more coagulation electrode(s) configured for sealing a severed vessel, such as an arterial vessel, and one or more electrode terminals configured for either contracting the collagen fibers within the tissue or removing (ablating) the tissue, e.g., by 25 applying sufficient energy to the tissue to effect molecular dissociation. In the latter embodiments, the coagulation electrode(s) may be configured such that a single voltage can be applied to coagulate with the coagulation electrode(s), and to ablate with the electrode terminal(s). In other embodiments, the power supply is combined with the coagulation instrument such that the coagulation electrode is used when the power supply is in the 30 coagulation mode (low voltage), and the electrode terminal(s) are used when the power supply is in the ablation mode (higher voltage).

In one method of the present invention, one or more electrode terminals are brought into close proximity to tissue at a target site, and the power supply is activated in

the ablation mode such that sufficient voltage is applied between the electrode terminals and the return electrode to volumetrically remove the tissue through molecular dissociation, as described below. During this process, vessels within the tissue will be severed. Smaller vessels will be automatically sealed with the system and method of the 5 present invention. Larger vessels, and those with a higher flow rate, such as arterial vessels, may not be automatically sealed in the ablation mode. In these cases, the severed vessels may be sealed by activating a control (e.g., a foot pedal) to reduce the voltage of the power supply into the coagulation mode. In this mode, the electrode terminals may be pressed against the severed vessel to provide sealing and/or coagulation of the vessel.

10 Alternatively, a coagulation electrode located on the same or a different instrument may be pressed against the severed vessel. Once the vessel is adequately sealed, the surgeon activates a control (e.g., another foot pedal) to increase the voltage of the power supply back into the ablation mode.

In some embodiments of the present invention, the tissue is purposely 15 damaged in a thermal heating mode to create necrosed or scarred tissue at the tissue surface. The high frequency voltage in the thermal heating mode is below the threshold of ablation as described above, but sufficient to cause some thermal damage to the tissue immediately surrounding the electrodes without vaporizing or otherwise debulking this tissue *in situ*. Typically, it is desired to achieve a tissue temperature in the range of about 20 60°C to 100°C to a depth of about 0.2 to 5 mm, usually about 1 to 2 mm. The voltage required for this thermal damage will partly depend on the electrode configurations, the conductivity of the area immediately surrounding the electrodes, the time period in which the voltage is applied and the depth of tissue damage desired. With the electrode 25 configurations described in this application (e.g., Figs. 15A-15D), the voltage level for thermal heating will usually be in the range of about 20 to 300 volts rms, preferably about 60 to 200 volts rms. The peak-to-peak voltages for thermal heating with a square wave form having a crest factor of about 2 are typically in the range of about 40 to 600 volts peak-to-peak, preferably about 120 to 400 volts peak-to-peak. The higher the voltage is within this range, the less time required. If the voltage is too high, however, the surface 30 tissue may be vaporized, debulked or ablated, which is undesirable.

In other embodiments, the present invention may be used for treating degenerative discs with fissures or tears. In these embodiments, the active and return electrode(s) are positioned in or around the inner wall of the disc annulus such that the

active electrode is adjacent to the fissure. High frequency voltage is applied between the active and return electrodes to heat the fissure and shrink the collagen fibers and create a seal or weld within the inner wall, thereby helping to close the fissure in the annulus. In these embodiments, the return electrode will typically be positioned proximally from the 5 active electrode(s) on the instrument shaft, and an electrically conductive fluid will be applied to the target site to create the necessary current path between the active and return electrodes. In alternative embodiments, the disc tissue may complete this electrically conductive path.

The present invention is also useful for removing or ablating tissue around 10 nerves, such as spinal, peripheral or cranial nerves. One of the significant drawbacks with the prior art shavers or microdebriders, conventional electrosurgical devices and lasers is that these devices do not differentiate between the target tissue and the surrounding nerves or bone. Therefore, the surgeon must be extremely careful during these procedures to avoid damage to the bone or nerves within and around the target site. In the present 15 invention, the Coblation® process for removing tissue results in extremely small depths of collateral tissue damage as discussed above. This allows the surgeon to remove tissue close to a nerve without causing collateral damage to the nerve fibers.

In addition to the generally precise nature of the novel mechanisms of the 20 present invention, applicant has discovered an additional method of ensuring that adjacent nerves are not damaged during tissue removal. According to the present invention, systems and methods are provided for distinguishing between the fatty tissue immediately surrounding nerve fibers and the normal tissue that is to be removed during the procedure.

Nerves usually comprise a connective tissue sheath, or epineurium, enclosing the bundles 25 of nerve fibers, each bundle being surrounded by its own sheath of connective tissue (the perineurium) to protect these nerve fibers. The outer protective tissue sheath or epineurium typically comprises a fatty tissue (e.g., adipose tissue) having substantially different electrical properties than the normal target tissue, such as the turbinates, polyps, mucus tissue or the like, that are, for example, removed from the nose during sinus procedures. The system of the present invention measures the electrical properties of the 30 tissue at the tip of the probe with one or more electrode terminal(s). These electrical properties may include electrical conductivity at one, several or a range of frequencies (e.g., in the range from 1 kHz to 100 MHz), dielectric constant, capacitance or combinations of these. In this embodiment, an audible signal may be produced when the

sensing electrode(s) at the tip of the probe detects the fatty tissue surrounding a nerve, or direct feedback control can be provided to only supply power to the electrode terminal(s) either individually or to the complete array of electrodes, if and when the tissue encountered at the tip or working end of the probe is normal tissue based on the measured
5 electrical properties.

In one embodiment, the current limiting elements (discussed in detail above) are configured such that the electrode terminals will shut down or turn off when the electrical impedance reaches a threshold level. When this threshold level is set to the impedance of the fatty tissue surrounding nerves, the electrode terminals will shut off
10 whenever they come in contact with, or in close proximity to, nerves. Meanwhile, the other electrode terminals, which are in contact with or in close proximity to tissue, will continue to conduct electric current to the return electrode. This selective ablation or removal of lower impedance tissue in combination with the Coblation® mechanism of the present invention allows the surgeon to precisely remove tissue around nerves or bone.
15 Applicant has found that the present invention is capable of volumetrically removing tissue closely adjacent to nerves without impairment the function of the nerves, and without significantly damaging the tissue of the epineurium. One of the significant drawbacks with the prior art microdebriders, conventional electrosurgical devices and lasers is that these devices do not differentiate between the target tissue and the surrounding nerves or bone.
20 Therefore, the surgeon must be extremely careful during these procedures to avoid damage to the bone or nerves within and around the nasal cavity. In the present invention, the Coblation® process for removing tissue results in extremely small depths of collateral tissue damage as discussed above. This allows the surgeon to remove tissue close to a nerve without causing collateral damage to the nerve fibers.

25 In addition to the above, applicant has discovered that the Coblation® mechanism of the present invention can be manipulated to ablate or remove certain tissue structures, while having little effect on other tissue structures. As discussed above, the present invention uses a technique of vaporizing electrically conductive fluid to form a plasma layer or pocket around the electrode terminal(s), and then inducing the discharge of
30 energy from this plasma or vapor layer to break the molecular bonds of the tissue structure. Based on initial experiments, applicants believe that the free electrons within the ionized vapor layer are accelerated in the high electric fields near the electrode tip(s). When the density of the vapor layer (or within a bubble formed in the electrically

conducting liquid) becomes sufficiently low (i.e., less than approximately 1020 atoms/cm³ for aqueous solutions), the electron mean free path increases to enable subsequently injected electrons to cause impact ionization within these regions of low density (i.e., vapor layers or bubbles). Energy evolved by the energetic electrons (e.g., 4 to 5 eV) can 5 subsequently bombard a molecule and break its bonds, dissociating a molecule into free radicals, which then combine into final gaseous or liquid species.

The energy evolved by the energetic electrons may be varied by adjusting a variety of factors, such as: the number of electrode terminals; electrode size and spacing; electrode surface area; asperities and sharp edges on the electrode surfaces; electrode 10 materials; applied voltage and power; current limiting means, such as inductors; electrical conductivity of the fluid in contact with the electrodes; density of the fluid; and other factors. Accordingly, these factors can be manipulated to control the energy level of the excited electrons. Since different tissue structures have different molecular bonds, the present invention can be configured to break the molecular bonds of certain tissue, while 15 having too low an energy to break the molecular bonds of other tissue. For example, fatty tissue, (e.g., adipose) tissue has double bonds that require a substantially higher energy level than 4 to 5 eV to break (typically on the order of about 8 eV). Accordingly, the present invention in its current configuration generally does not ablate or remove such fatty tissue. Of course, factors may be changed such that these double bonds can also be broken 20 in a similar fashion as the single bonds (e.g., increasing voltage or changing the electrode configuration to increase the current density at the electrode tips). A more complete description of this phenomena can be found in co-pending U.S. Patent Application 09/032,375, filed February 27, 1998 (Attorney Docket No. CB-3), the complete disclosure of which is incorporated herein by reference.

25 The present invention also provides systems, apparatus and methods for selectively removing tumors, e.g., facial tumors, or other undesirable body structures while minimizing the spread of viable cells from the tumor. Conventional techniques for removing such tumors generally result in the production of smoke in the surgical setting, termed an electrosurgical or laser plume, which can spread intact, viable bacterial or viral particles from the tumor or lesion to the surgical team or to other portions of the patient's 30 body. This potential spread of viable cells or particles has resulted in increased concerns over the proliferation of certain debilitating and fatal diseases, such as hepatitis, herpes, HIV and papillomavirus. In the present invention, high frequency voltage is applied

between the electrode terminal(s) and one or more return electrode(s) to volumetrically remove at least a portion of the tissue cells in the tumor through the dissociation or disintegration of organic molecules into non-viable atoms and molecules. Specifically, the present invention converts the solid tissue cells into non-condensable gases that are no longer intact or viable, and thus, not capable of spreading viable tumor particles to other portions of the patient's brain or to the surgical staff. The high frequency voltage is preferably selected to effect controlled removal of these tissue cells while minimizing substantial tissue necrosis to surrounding or underlying tissue. A more complete description of this phenomena can be found in co-pending U.S. Patent Application 10 09/109,219, filed June 30, 1998 (Attorney Docket No. CB-1), the complete disclosure of which is incorporated herein by reference.

In other procedures, it may be desired to shrink or contract collagen connective tissue within the disc. In these procedures, the RF energy heats the disc tissue directly by virtue of the electrical current flow therethrough, and/or indirectly through the exposure of the tissue to fluid heated by RF energy, to elevate the tissue temperature from normal body temperatures (e.g., 37°C) to temperatures in the range of 45°C to 90°C, preferably in the range from about 60°C to 70°C. Thermal shrinkage of collagen fibers occurs within a small temperature range which, for mammalian collagen is in the range from 60°C to 70°C (Deak, G., et al., "The Thermal Shrinkage Process of Collagen Fibres as Revealed by Polarization Optical Analysis of Topooptical Staining Reactions," Acta Morphologica Acad. Sci. of Hungary, Vol. 15(2), pp 195-208, 1967). Collagen fibers typically undergo thermal shrinkage in the range of 60°C to about 70°C. Previously reported research has attributed thermal shrinkage of collagen to the cleaving of the internal stabilizing cross-linkages within the collagen matrix (Deak, ibid). It has also been reported that when the collagen temperature is increased above 70°C, the collagen matrix begins to relax again and the shrinkage effect is reversed resulting in no net shrinkage (Allain, J. C., et al., "Isometric Tensions Developed During the Hydrothermal Swelling of Rat Skin," Connective Tissue Research, Vol. 7, pp 127-133, 1980). Consequently, the controlled heating of tissue to a precise depth is critical to the achievement of therapeutic collagen shrinkage. A more detailed description of collagen shrinkage can be found in U.S. Patent Application No. 08/942,580 filed on October 2, 1997, (Attorney Docket No. 30 16238-001300).

The preferred depth of heating to effect the shrinkage of collagen in the

heated region (i.e., the depth to which the tissue is elevated to temperatures between 60°C to 70°C) generally depends on (1) the thickness of the disc, (2) the location of nearby structures (e.g., nerves) that should not be exposed to damaging temperatures, and/or (3) the location of the collagen tissue layer within which therapeutic shrinkage is to be effected. The depth of heating is usually in the range from 1.0 to 5.0 mm.

The electrosurgical probe or catheter will comprise a shaft or a handpiece having a proximal end and a distal end which supports one or more electrode terminal(s). The shaft or handpiece may assume a wide variety of configurations, with the primary purpose being to mechanically support the active electrode and permit the treating physician to manipulate the electrode from a proximal end of the shaft. The shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end of the shaft to facilitate positioning of the electrode array. The shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode array to a connector at the proximal end of the shaft.

For endoscopic procedures within the spine, the shaft will have a suitable diameter and length to allow the surgeon to reach the target site (e.g., a disc) by delivering the shaft through the thoracic cavity, the abdomen or the like. Thus, the shaft will usually have a length in the range of about 5.0 to 30.0 cm, and a diameter in the range of about 0.2 mm to about 20 mm. Alternatively, the shaft may be delivered directly through the patient's back in a posterior approach, which would considerably reduce the required length of the shaft. In any of these embodiments, the shaft may also be introduced through rigid or flexible endoscopes. Alternatively, the shaft may be a flexible catheter that is introduced through a percutaneous penetration in the patient. Specific shaft designs will be described in detail in connection with the figures hereinafter.

In an alternative embodiment, the probe may comprise a long, thin needle (e.g., on the order of about 1 mm in diameter or less) that can be percutaneously introduced through the patient's back directly into the spine. The needle will include one or more active electrode(s) for applying electrical energy to tissues within the spine. The needle may include one or more return electrode(s), or the return electrode may be positioned on the patient's back, as a dispersive pad. In either embodiment, sufficient

electrical energy is applied through the needle to the active electrode(s) to either shrink the collagen fibers within the spinal disc, or to ablate tissue within the disc.

The electrosurgical instrument may also be a catheter that is delivered percutaneously and/or endoluminally into the patient by insertion through a conventional 5 or specialized guide catheter, or the invention may include a catheter having an active electrode or electrode array integral with its distal end. The catheter shaft may be rigid or flexible, with flexible shafts optionally being combined with a generally rigid external tube for mechanical support. Flexible shafts may be combined with pull wires, shape memory actuators, and other known mechanisms for effecting selective deflection of the distal end 10 of the shaft to facilitate positioning of the electrode or electrode array. The catheter shaft will usually include a plurality of wires or other conductive elements running axially therethrough to permit connection of the electrode or electrode array and the return electrode to a connector at the proximal end of the catheter shaft. The catheter shaft may include a guide wire for guiding the catheter to the target site, or the catheter may 15 comprise a steerable guide catheter. The catheter may also include a substantially rigid distal end portion to increase the torque control of the distal end portion as the catheter is advanced further into the patient's body. Specific shaft designs will be described in detail in connection with the figures hereinafter.

The electrode terminal(s) are preferably supported within or by an inorganic 20 insulating support positioned near the distal end of the instrument shaft. The return electrode may be located on the instrument shaft, on another instrument or on the external surface of the patient (i.e., a dispersive pad). The close proximity of nerves and other sensitive tissue in and around the spinal cord, however, makes a bipolar design more preferable because this minimizes the current flow through non-target tissue and 25 surrounding nerves. Accordingly, the return electrode is preferably either integrated with the instrument body, or another instrument located in close proximity thereto. The proximal end of the instrument(s) will include the appropriate electrical connections for coupling the return electrode(s) and the electrode terminal(s) to a high frequency power supply, such as an electrosurgical generator.

In some embodiments, the active electrode(s) have an active portion or 30 surface with surface geometries shaped to promote the electric field intensity and associated current density along the leading edges of the electrodes. Suitable surface geometries may be obtained by creating electrode shapes that include preferential sharp

edges, or by creating asperities or other surface roughness on the active surface(s) of the electrodes. Electrode shapes according to the present invention can include the use of formed wire (e.g., by drawing round wire through a shaping die) to form electrodes with a variety of cross-sectional shapes, such as square, rectangular, L or V shaped, or the like.

5 Electrode edges may also be created by removing a portion of the elongate metal electrode to reshape the cross-section. For example, material can be ground along the length of a round or hollow wire electrode to form D or C shaped wires, respectively, with edges facing in the cutting direction. Alternatively, material can be removed at closely spaced intervals along the electrode length to form transverse grooves, slots, threads or the like

10 along the electrodes.

Additionally or alternatively, the active electrode surface(s) may be modified through chemical, electrochemical or abrasive methods to create a multiplicity of surface asperities on the electrode surface. These surface asperities will promote high electric field intensities between the active electrode surface(s) and the target tissue to facilitate ablation or cutting of the tissue. For example, surface asperities may be created by etching the active electrodes with etchants having a Ph less than 7.0 or by using a high velocity stream of abrasive particles (e.g., grit blasting) to create asperities on the surface of an elongated electrode. A more detailed description of such electrode configurations can be found in U.S. Patent No. 5,843,019, the complete disclosure of which is

15 incorporated herein by reference.

20

The return electrode is typically spaced proximally from the active electrode(s) a suitable distance to avoid electrical shorting between the active and return electrodes in the presence of electrically conductive fluid. In most of the embodiments described herein, the distal edge of the exposed surface of the return electrode is spaced about 0.5 to 25 mm from the proximal edge of the exposed surface of the active electrode(s), preferably about 1.0 to 5.0 mm. Of course, this distance may vary with different voltage ranges, conductive fluids, and depending on the proximity of tissue structures to active and return electrodes. The return electrode will typically have an exposed length in the range of about 1 to 20 mm.

25

30 The current flow path between the electrode terminals and the return electrode(s) may be generated by submerging the tissue site in an electrical conducting fluid (e.g., within a viscous fluid, such as an electrically conductive gel) or by directing an electrically conducting fluid along a fluid path to the target site (i.e., a liquid, such as

isotonic saline, hypotonic saline or a gas, such as argon). The conductive gel may also be delivered to the target site to achieve a slower more controlled delivery rate of conductive fluid. In addition, the viscous nature of the gel may allow the surgeon to more easily contain the gel around the target site (e.g., rather than attempting to contain isotonic saline). A more complete description of an exemplary method of directing electrically conducting fluid between the active and return electrodes is described in U.S. Patent No. 5,697,281, previously incorporated herein by reference. Alternatively, the body's natural conductive fluids, such as blood or intracellular saline, may be sufficient to establish a conductive path between the return electrode(s) and the electrode terminal(s), and to provide the conditions for establishing a vapor layer, as described above. However, conductive fluid that is introduced into the patient is generally preferred over blood because blood will tend to coagulate at certain temperatures. In addition, the patient's blood may not have sufficient electrical conductivity to adequately form a plasma in some applications. Advantageously, a liquid electrically conductive fluid (e.g., isotonic saline) may be used to concurrently "bathe" the target tissue surface to provide an additional means for removing any tissue, and to cool the region of the target tissue ablated in the previous moment.

The power supply may include a fluid interlock for interrupting power to the electrode terminal(s) when there is insufficient conductive fluid around the electrode terminal(s). This ensures that the instrument will not be activated when conductive fluid is not present, minimizing the tissue damage that may otherwise occur. A more complete description of such a fluid interlock can be found in commonly assigned, co-pending U.S. Application NO. 09/058,336, filed April 10, 1998 (attorney Docket No. CB-4), the complete disclosure of which is incorporated herein by reference.

In some procedures, it may also be necessary to retrieve or aspirate the electrically conductive fluid and/or the non-condensable gaseous products of ablation. In addition, it may be desirable to aspirate small pieces of tissue or other body structures that are not completely disintegrated by the high frequency energy, or other fluids at the target site, such as blood, mucus, the gaseous products of ablation, etc. Accordingly, the system of the present invention may include one or more suction lumen(s) in the instrument, or on another instrument, coupled to a suitable vacuum source for aspirating fluids from the target site. In addition, the invention may include one or more aspiration electrode(s) coupled to the distal end of the suction lumen for ablating, or at least reducing the volume

of, non-ablated tissue fragments that are aspirated into the lumen. The aspiration electrode(s) function mainly to inhibit clogging of the lumen that may otherwise occur as larger tissue fragments are drawn therein. The aspiration electrode(s) may be different from the ablation electrode terminal(s), or the same electrode(s) may serve both functions.

5 A more complete description of instruments incorporating aspiration electrode(s) can be found in commonly assigned, co-pending patent application entitled "Systems And Methods For Tissue Resection, Ablation And Aspiration", filed January 21, 1998, the complete disclosure of which is incorporated herein by reference.

As an alternative or in addition to suction, it may be desirable to contain the
10 excess electrically conductive fluid, tissue fragments and/or gaseous products of ablation at or near the target site with a containment apparatus, such as a basket, retractable sheath or the like. This embodiment has the advantage of ensuring that the conductive fluid, tissue fragments or ablation products do not flow through the patient's vasculature or into other portions of the body. In addition, it may be desirable to limit the amount of suction to
15 limit the undesirable effect suction may have on hemostasis of severed blood vessels.

The present invention may use a single active electrode terminal or an array
20 of electrode terminals spaced around the distal surface of a catheter or probe. In the latter embodiment, the electrode array usually includes a plurality of independently current-limited and/or power-controlled electrode terminals to apply electrical energy selectively to the target tissue while limiting the unwanted application of electrical energy to the surrounding tissue and environment resulting from power dissipation into surrounding electrically conductive fluids, such as blood, normal saline, and the like. The electrode terminals may be independently current-limited by isolating the terminals from each other and connecting each terminal to a separate power source that is isolated from the other
25 electrode terminals. Alternatively, the electrode terminals may be connected to each other at either the proximal or distal ends of the catheter to form a single wire that couples to a power source.

In one configuration, each individual electrode terminal in the electrode array is electrically insulated from all other electrode terminals in the array within said
30 instrument and is connected to a power source which is isolated from each of the other electrode terminals in the array or to circuitry which limits or interrupts current flow to the electrode terminal when low resistivity material (*e.g.*, blood, electrically conductive saline irrigant or electrically conductive gel) causes a lower impedance path between the return

electrode and the individual electrode terminal. The isolated power sources for each individual electrode terminal may be separate power supply circuits having internal impedance characteristics which limit power to the associated electrode terminal when a low impedance return path is encountered. By way of example, the isolated power source 5 may be a user selectable constant current source. In this embodiment, lower impedance paths will automatically result in lower resistive heating levels since the heating is proportional to the square of the operating current times the impedance. Alternatively, a single power source may be connected to each of the electrode terminals through independently actuatable switches, or by independent current limiting elements, such as 10 inductors, capacitors, resistors and/or combinations thereof. The current limiting elements may be provided in the instrument, connectors, cable, controller or along the conductive path from the controller to the distal tip of the instrument. Alternatively, the resistance and/or capacitance may occur on the surface of the active electrode terminal(s) due to 15 oxide layers which form selected electrode terminals (e.g., titanium or a resistive coating on the surface of metal, such as platinum).

The tip region of the instrument may comprise many independent electrode terminals designed to deliver electrical energy in the vicinity of the tip. The selective application of electrical energy to the conductive fluid is achieved by connecting each individual electrode terminal and the return electrode to a power source having 20 independently controlled or current limited channels. The return electrode(s) may comprise a single tubular member of conductive material proximal to the electrode array at the tip which also serves as a conduit for the supply of the electrically conducting fluid between the active and return electrodes. Alternatively, the instrument may comprise an array of return electrodes at the distal tip of the instrument (together with the active 25 electrodes) to maintain the electric current at the tip. The application of high frequency voltage between the return electrode(s) and the electrode array results in the generation of high electric field intensities at the distal tips of the electrode terminals with conduction of high frequency current from each individual electrode terminal to the return electrode. The current flow from each individual electrode terminal to the return electrode(s) is 30 controlled by either active or passive means, or a combination thereof, to deliver electrical energy to the surrounding conductive fluid while minimizing energy delivery to surrounding (non-target) tissue.

The application of a high frequency voltage between the return electrode(s) and the electrode terminal(s) for appropriate time intervals effects cutting, removing, ablating, shaping, contracting or otherwise modifying the target tissue. In some embodiments of the present invention, the tissue volume over which energy is dissipated (i.e., a high current density exists) may be more precisely controlled, for example, by the use of a multiplicity of small electrode terminals whose effective diameters or principal dimensions range from about 10 mm to 0.01 mm, preferably from about 2 mm to 0.05 mm, and more preferably from about 1 mm to 0.1 mm. In this embodiment, electrode areas for both circular and non-circular terminals will have a contact area (per electrode terminal) below 50 mm² for electrode arrays and as large as 75 mm² for single electrode embodiments. In multiple electrode array embodiments, the contact area of each electrode terminal is typically in the range from 0.0001 mm² to 1 mm², and more preferably from 0.001 mm² to .5 mm². The circumscribed area of the electrode array or electrode terminal is in the range from 0.25 mm² to 75 mm², preferably from 0.5 mm² to 40 mm².

In multiple electrode embodiments, the array will usually include at least two isolated electrode terminals, often at least five electrode terminals, often greater than 10 electrode terminals and even 50 or more electrode terminals, disposed over the distal contact surfaces on the shaft. The use of small diameter electrode terminals increases the electric field intensity and reduces the extent or depth of tissue heating as a consequence of the divergence of current flux lines which emanate from the exposed surface of each electrode terminal.

The area of the tissue treatment surface can vary widely, and the tissue treatment surface can assume a variety of geometries, with particular areas and geometries being selected for specific applications. The geometries can be planar, concave, convex, hemispherical, conical, linear "in-line" array or virtually any other regular or irregular shape. Most commonly, the active electrode(s) or electrode terminal(s) will be formed at the distal tip of the electrosurgical instrument shaft, frequently being planar, disk-shaped, or hemispherical surfaces for use in reshaping procedures or being linear arrays for use in cutting. Alternatively or additionally, the active electrode(s) may be formed on lateral surfaces of the electrosurgical instrument shaft (e.g., in the manner of a spatula), facilitating access to certain body structures in endoscopic procedures.

In some embodiments, the electrode support and the fluid outlet may be recessed from an outer surface of the instrument or handpiece to confine the electrically

conductive fluid to the region immediately surrounding the electrode support. In addition, the shaft may be shaped so as to form a cavity around the electrode support and the fluid outlet. This helps to assure that the electrically conductive fluid will remain in contact with the electrode terminal(s) and the return electrode(s) to maintain the conductive path therebetween. In addition, this will help to maintain a vapor layer and subsequent plasma layer between the electrode terminal(s) and the tissue at the treatment site throughout the procedure, which reduces the thermal damage that might otherwise occur if the vapor layer were extinguished due to a lack of conductive fluid. Provision of the electrically conductive fluid around the target site also helps to maintain the tissue temperature at desired levels.

In other embodiments, the active electrodes are spaced from the tissue a sufficient distance to minimize or avoid contact between the tissue and the vapor layer formed around the active electrodes. In these embodiments, contact between the heated electrons in the vapor layer and the tissue is minimized as these electrons travel from the vapor layer back through the conductive fluid to the return electrode. The ions within the plasma, however, will have sufficient energy, under certain conditions such as higher voltage levels, to accelerate beyond the vapor layer to the tissue. Thus, the tissue bonds are dissociated or broken as in previous embodiments, while minimizing the electron flow, and thus the thermal energy, in contact with the tissue.

The electrically conducting fluid should have a threshold conductivity to provide a suitable conductive path between the return electrode and the electrode terminal(s). The electrical conductivity of the fluid (in units of millSiemens per centimeter or mS/cm) will usually be greater than 0.2 mS/cm, preferably will be greater than 2 mS/cm and more preferably greater than 10 mS/cm. In an exemplary embodiment, the electrically conductive fluid is isotonic saline, which has a conductivity of about 17 mS/cm. Applicant has found that a more conductive fluid, or one with a higher ionic concentration, will usually provide a more aggressive ablation rate. For example, a saline solution with higher levels of sodium chloride than conventional saline (which is on the order of about .9% sodium chloride) e.g., on the order of greater than 1% or between about 3% and 20%, may be desirable. Alternatively, the invention may be used with different types of conductive fluids that increase the power of the plasma layer by, for example, increasing the quantity of ions in the plasma, or by providing ions that have higher energy levels than sodium ions. For example, the present invention may be used

with elements other than sodium, such as potassium, magnesium, calcium and other metals near the left end of the periodic chart. In addition, other electronegative elements may be used in place of chlorine, such as fluorine.

The voltage difference applied between the return electrode(s) and the electrode terminal(s) will be at high or radio frequency, typically between about 5 kHz and 20 MHz, usually being between about 30 kHz and 2.5 MHz, preferably being between about 50 kHz and 500 kHz, often less than 350 kHz, and often between about 100 kHz and 200 kHz. In some applications, applicant has found that a frequency of about 100 kHz is useful because the tissue impedance is much greater at this frequency. In other applications, such as procedures in or around the heart or head and neck, higher frequencies may be desirable (e.g., 400-600 kHz) to minimize low frequency current flow into the heart or the nerves of the head and neck. The RMS (root mean square) voltage applied will usually be in the range from about 5 volts to 1000 volts, preferably being in the range from about 10 volts to 500 volts, often between about 150 to 400 volts depending on the electrode terminal size, the operating frequency and the operation mode of the particular procedure or desired effect on the tissue (i.e., contraction, coagulation, cutting or ablation). Typically, the peak-to-peak voltage for ablation or cutting with a square wave form will be in the range of 10 to 2000 volts and preferably in the range of 100 to 1800 volts and more preferably in the range of about 300 to 1500 volts, often in the range of about 300 to 800 volts peak to peak (again, depending on the electrode size, number of electrons, the operating frequency and the operation mode). Lower peak-to-peak voltages will be used for tissue coagulation, thermal heating of tissue, or collagen contraction and will typically be in the range from 50 to 1500, preferably 100 to 1000 and more preferably 120 to 400 volts peak-to-peak (again, these values are computed using a square wave form). Higher peak-to-peak voltages, e.g., greater than about 800 volts peak-to-peak, may be desirable for ablation of harder material, such as bone, depending on other factors, such as the electrode geometries and the composition of the conductive fluid.

As discussed above, the voltage is usually delivered in a series of voltage pulses or alternating current of time varying voltage amplitude with a sufficiently high frequency (e.g., on the order of 5 kHz to 20 MHz) such that the voltage is effectively applied continuously (as compared with e.g., lasers claiming small depths of necrosis, which are generally pulsed about 10 to 20 Hz). In addition, the duty cycle (i.e., cumulative time in any one-second interval that energy is applied) is on the order of about

50% for the present invention, as compared with pulsed lasers which typically have a duty cycle of about 0.0001%.

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from several milliwatts to tens of watts per electrode, depending on the volume of target tissue being heated, and/or the maximum allowed temperature selected for the instrument tip. The power source allows the user to select the voltage level according to the specific requirements of a particular neurosurgery procedure, cardiac surgery, arthroscopic surgery, dermatological procedure, ophthalmic procedures, open surgery or other endoscopic surgery procedure. For cardiac procedures and potentially for neurosurgery, the power source may have an additional filter, for filtering leakage voltages at frequencies below 100 kHz, particularly voltages around 60 kHz. Alternatively, a power source having a higher operating frequency, e.g., 300 to 600 kHz may be used in certain procedures in which stray low frequency currents may be problematic. A description of one suitable power source can be found in co-pending Patent Applications 09/058,571 and 09/058,336, filed April 10, 1998 (Attorney Docket Nos. CB-2 and CB-4), the complete disclosure of both applications are incorporated herein by reference for all purposes.

The power source may be current limited or otherwise controlled so that undesired heating of the target tissue or surrounding (non-target) tissue does not occur. In a presently preferred embodiment of the present invention, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in the range of 10uH to 50,000uH, depending on the electrical properties of the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in U.S. Patent No. 5,697,909, the complete disclosure of which is incorporated herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode terminal in contact with a low resistance medium (e.g., saline irrigant or blood), the resistance of the current limiting resistor increases significantly, thereby minimizing the power delivery from said electrode terminal into the low resistance medium (e.g., saline irrigant or blood).

It should be clearly understood that the invention is not limited to electrically isolated electrode terminals, or even to a plurality of electrode terminals. For

example, the array of active electrode terminals may be connected to a single lead that extends through the catheter shaft to a power source of high frequency current.

Alternatively, the instrument may incorporate a single electrode that extends directly through the catheter shaft or is connected to a single lead that extends to the power source.

- 5 The active electrode(s) may have ball shapes (e.g., for tissue vaporization and desiccation), twizzle shapes (for vaporization and needle-like cutting), spring shapes (for rapid tissue debulking and desiccation), twisted metal shapes, annular or solid tube shapes or the like. Alternatively, the electrode(s) may comprise a plurality of filaments, rigid or flexible brush electrode(s) (for debulking a tumor, such as a fibroid, bladder tumor or a prostate adenoma), side-effect brush electrode(s) on a lateral surface of the shaft, coiled electrode(s) or the like.
- 10

Referring to Fig. 1, an exemplary electrosurgical system 11 for treatment of tissue in the spine will now be described in detail. Electrosurgical system 11 generally comprises an electrosurgical handpiece or probe 10 connected to a power supply 28 for providing high frequency voltage to a target site and a fluid source 21 for supplying electrically conducting fluid 50 to probe 10. In addition, electrosurgical system 11 may include an endoscope (not shown) with a fiber optic head light for viewing the surgical site. The endoscope may be integral with probe 10, or it may be part of a separate instrument. The system 11 may also include a vacuum source (not shown) for coupling to a suction lumen or tube 205 (see Fig. 2) in the probe 10 for aspirating the target site.

As shown, probe 10 generally includes a proximal handle 19 and an elongate shaft 18 having an array 12 of electrode terminals 58 at its distal end. A connecting cable 34 has a connector 26 for electrically coupling the electrode terminals 58 to power supply 28. The electrode terminals 58 are electrically isolated from each other and each of the terminals 58 is connected to an active or passive control network within power supply 28 by means of a plurality of individually insulated conductors (not shown).

A fluid supply tube 15 is connected to a fluid tube 14 of probe 10 for supplying electrically conducting fluid 50 to the target site. Fluid supply tube 15 may be connected to a suitable pump (not shown), if desired.

30 Power supply 28 has an operator controllable voltage level adjustment 30 to change the applied voltage level, which is observable at a voltage level display 32. Power supply 28 also includes first, second and third foot pedals 37, 38, 39 and a cable 36 which is removably coupled to power supply 28. The foot pedals 37, 38, 39 allow the surgeon to

remotely adjust the energy level applied to electrode terminals 58. In an exemplary embodiment, first foot pedal 37 is used to place the power supply into the "ablation" mode and second foot pedal 38 places power supply 28 into the "sub-ablation" mode (e.g., coagulation or contraction of tissue). The third foot pedal 39 allows the user to adjust the
5 voltage level within the "ablation" mode. In the ablation mode, a sufficient voltage is applied to the electrode terminals to establish the requisite conditions for molecular dissociation of the tissue (i.e., vaporizing a portion of the electrically conductive fluid, ionizing charged particles within the vapor layer and accelerating these charged particles against the tissue). As discussed above, the requisite voltage level for ablation will vary
10 depending on the number, size, shape and spacing of the electrodes, the distance in which the electrodes extend from the support member, etc. Once the surgeon places the power supply in the "ablation" mode, voltage level adjustment 30 or third foot pedal 39 may be used to adjust the voltage level to adjust the degree or aggressiveness of the ablation.

Of course, it will be recognized that the voltage and modality of the power
15 supply may be controlled by other input devices. However, applicant has found that foot pedals are convenient methods of controlling the power supply while manipulating the probe during a surgical procedure.

In the subablation mode, the power supply 28 applies a low enough voltage to the electrode terminals to avoid vaporization of the electrically conductive fluid and
20 subsequent molecular dissociation of the tissue. The surgeon may automatically toggle the power supply between the ablation and sub-ablation modes by alternatively stepping on foot pedals 37, 38, respectively. In some embodiments, this allows the surgeon to quickly move between coagulation/thermal heating and ablation *in situ*, without having to remove his/her concentration from the surgical field or without having to request an assistant to
25 switch the power supply. By way of example, as the surgeon is sculpting soft tissue in the ablation mode, the probe typically will simultaneously seal and/or coagulate small severed vessels within the tissue. However, larger vessels, or vessels with high fluid pressures (e.g., arterial vessels) may not be sealed in the ablation mode. Accordingly, the surgeon can simply step on foot pedal 38, automatically lowering the voltage level below
30 the threshold level for ablation, and apply sufficient pressure onto the severed vessel for a sufficient period of time to seal and/or coagulate the vessel. After this is completed, the surgeon may quickly move back into the ablation mode by stepping on foot pedal 37.

Referring now to Fig. 2 and 3, a representative high frequency power supply for use according to the principles of the present invention will now be described. The high frequency power supply of the present invention is configured to apply a high frequency voltage of about 10 to 500 volts RMS between one or more electrode terminals (and/or coagulation electrode) and one or more return electrodes. In the exemplary embodiment, the power supply applies about 70-350 volts RMS in the ablation mode and about 20 to 90 volts in a subablation mode, preferably 45 to 70 volts in the subablation mode (these values will, of course, vary depending on the probe configuration attached to the power supply and the desired mode of operation).

The preferred power source of the present invention delivers a high frequency current selectable to generate average power levels ranging from several milliwatts to tens of watts per electrode, depending on the volume of target tissue being heated, and/or the maximum allowed temperature selected for the probe tip. The power source allows the user to select the voltage level according to the specific requirements of a particular procedure, e.g., arthroscopic surgery, dermatological procedure, ophthalmic procedures, open surgery or other endoscopic surgery procedure.

As shown in Fig. 2, the power supply generally comprises a radio frequency (RF) power oscillator 100 having output connections for coupling via a power output signal 102 to the load impedance, which is represented by the electrode assembly when the electrosurgical probe is in use. In the representative embodiment, the RF oscillator operates at about 100 kHz. The RF oscillator is not limited to this frequency and may operate at frequencies of about 300kHz to 600kHz. In particular, for cardiac applications, the RF oscillator will preferably operate in the range of about 400 kHz to about 600 kHz.

The RF oscillator will generally supply a square wave signal with a crest factor of about 1 to 2. Of course, this signal may be a sine wave signal or other suitable wave signal depending on the application and other factors, such as the voltage applied, the number and geometry of the electrodes, etc. The power output signal 102 is designed to incur minimal voltage decrease (i.e., sag) under load. This improves the applied voltage to the electrode terminals and the return electrode, which improves the rate of volumetric removal (ablation) of tissue.

Power is supplied to the oscillator 100 by a switching power supply 104 coupled between the power line and the RF oscillator rather than a conventional transformer. The switching power supply 140 allows the generator to achieve high peak

power output without the large size and weight of a bulky transformer. The architecture of the switching power supply also has been designed to reduce electromagnetic noise such that U.S. and foreign EMI requirements are met. This architecture comprises a zero voltage switching or crossing, which causes the transistors to turn ON and OFF when the 5 voltage is zero. Therefore, the electromagnetic noise produced by the transistors switching is vastly reduced. In an exemplary embodiment, the switching power supply 104 operates at about 100 kHz.

A controller 106 coupled to the operator controls 105 (i.e., foot pedals and voltage selector) and display 116, is connected to a control input of the switching power 10 supply 104 for adjusting the generator output power by supply voltage variation. The controller 106 may be a microprocessor or an integrated circuit. The power supply may also include one or more current sensors 112 for detecting the output current. The power supply is preferably housed within a metal casing which provides a durable enclosure for the electrical components therein. In addition, the metal casing reduces the 15 electromagnetic noise generated within the power supply because the grounded metal casing functions as a "Faraday shield", thereby shielding the environment from internal sources of electromagnetic noise.

The power supply generally comprises a main or mother board containing generic electrical components required for many different surgical procedures (e.g., arthroscopy, urology, general surgery, dermatology, neurosurgery, etc.), and a daughter 20 board containing application specific current-limiting circuitry (e.g., inductors, resistors, capacitors and the like). The daughter board is coupled to the mother board by a detachable multi-pin connector to allow convenient conversion of the power supply to, e.g., applications requiring a different current limiting circuit design. For arthroscopy, for 25 example, the daughter board preferably comprises a plurality of inductors of about 200 to 400 microhenries, usually about 300 microhenries, for each of the channels supplying current to the electrode terminals 02 (see Fig. 2).

Alternatively, in one embodiment, current limiting inductors are placed in series with each independent electrode terminal, where the inductance of the inductor is in 30 the range of 10uH to 50,000uH, depending on the electrical properties of the target tissue, the desired tissue heating rate and the operating frequency. Alternatively, capacitor-inductor (LC) circuit structures may be employed, as described previously in co-pending PCT application No. PCT/US94/05168, the complete disclosure of which is incorporated

herein by reference. Additionally, current limiting resistors may be selected. Preferably, these resistors will have a large positive temperature coefficient of resistance so that, as the current level begins to rise for any individual electrode terminal in contact with a low resistance medium (e.g., saline irrigant or conductive gel), the resistance of the current 5 limiting resistor increases significantly, thereby minimizing the power delivery from said electrode terminal into the low resistance medium (e.g., saline irrigant or conductive gel).

Power output signal may also be coupled to a plurality of current limiting elements 96, which are preferably located on the daughter board since the current limiting elements may vary depending on the application. A more complete description of a representative power 10 supply can be found in commonly assigned U.S. Patent Application No. 09/058,571, previously incorporated herein by reference.

Figs. 4-6 illustrate an exemplary electrosurgical probe 20 constructed according to the principles of the present invention. As shown in Fig. 4, probe 90 generally includes an elongated shaft 100 which may be flexible or rigid, a handle 204 coupled to the proximal end of shaft 100 and an electrode support member 102 coupled to the distal end of shaft 100. Shaft 100 preferably comprises an electrically conducting material, usually metal, which is selected from the group comprising tungsten, stainless steel alloys, platinum or its alloys, titanium or its alloys, molybdenum or its alloys, and nickel or its alloys. In this embodiment, shaft 100 includes an electrically insulating jacket 15 108, which is typically formed as one or more electrically insulating sheaths or coatings, such as polytetrafluoroethylene, polyimide, and the like. The provision of the electrically insulating jacket over the shaft prevents direct electrical contact between these metal elements and any adjacent body structure or the surgeon. Such direct electrical contact 20 between a body structure (e.g., tendon) and an exposed electrode could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis. Alternatively, the return electrode may comprise an annular band coupled to an insulating shaft and having a connector extending within the shaft to its proximal end.

Handle 204 typically comprises a plastic material that is easily molded into a suitable shape for handling by the surgeon. Handle 204 defines an inner cavity (not 30 shown) that houses the electrical connections 250 (Fig. 6), and provides a suitable interface for connection to an electrical connecting cable 22 (see Fig. 1). Electrode support member 102 extends from the distal end of shaft 100 (usually about 1 to 20 mm), and provides support for a plurality of electrically isolated electrode terminals 104 (see Fig. 5). As

shown in Fig. 4, a fluid tube 233 extends through an opening in handle 204, and includes a connector 235 for connection to a fluid supply source, for supplying electrically conductive fluid to the target site. Depending on the configuration of the distal surface of shaft 100, fluid tube 233 may extend through a single lumen (not shown) in shaft 100, or it may be coupled to a plurality of lumens (also not shown) that extend through shaft 100 to a plurality of openings at its distal end. In the representative embodiment, fluid tube 239 is a plastic tubing that extends along the exterior of shaft 100 to a point just distal of return electrode 112 (see Fig. 5). In this embodiment, the fluid is directed through an opening 237 past return electrode 112 to the electrode terminals 104. Probe 20 may also include a valve 17 (Fig. 1) or equivalent structure for controlling the flow rate of the electrically conducting fluid to the target site.

As shown in Fig. 4, the distal portion of shaft 100 is preferably bent to improve access to the operative site of the tissue being treated. Electrode support member 102 has a substantially planar tissue treatment surface 212 (Fig. 5) that is usually at an angle of about 10 to 90 degrees relative to the longitudinal axis of shaft 100, preferably about 30 to 60 degrees and more preferably about 45 degrees. In alternative embodiments, the distal portion of shaft 100 comprises a flexible material which can be deflected relative to the longitudinal axis of the shaft. Such deflection may be selectively induced by mechanical tension of a pull wire, for example, or by a shape memory wire that expands or contracts by externally applied temperature changes. A more complete description of this embodiment can be found in U.S. Patent No. 5, 697,909, the complete disclosure of which has previously been incorporated herein by reference. Alternatively, the shaft 100 of the present invention may be bent by the physician to the appropriate angle using a conventional bending tool or the like.

In the embodiment shown in Figs. 4-6, probe 20 includes a return electrode 112 for completing the current path between electrode terminals 104 and a high frequency power supply 28 (see Fig. 1). As shown, return electrode 112 preferably comprises an exposed portion of shaft 100 shaped as an annular conductive band near the distal end of shaft 100 slightly proximal to tissue treatment surface 212 of electrode support member 102, typically about 0.5 to 10 mm and more preferably about 1 to 10 mm. Return electrode 112 or shaft 100 is coupled to a connector 258 that extends to the proximal end of probe 10, where it is suitably connected to power supply 10 (Fig. 1).

As shown in Fig. 4, return electrode 112 is not directly connected to electrode terminals 104. To complete this current path so that electrode terminals 104 are electrically connected to return electrode 112, electrically conducting fluid (e.g., isotonic saline) is caused to flow therebetween. In the representative embodiment, the electrically conducting fluid is delivered through fluid tube 233 to opening 237, as described above. Alternatively, the fluid may be delivered by a fluid delivery element (not shown) that is separate from probe 20. In arthroscopic surgery, for example, the body cavity will be flooded with isotonic saline and the probe 90 will be introduced into this flooded cavity. Electrically conducting fluid will be continually resupplied to maintain the conduction path between return electrode 112 and electrode terminals 104. In other embodiments, the distal portion of probe 20 may be dipped into a source of electrically conductive fluid, such as a gel or isotonic saline, prior to positioning at the target site. Applicant has found that the surface tension of the fluid and/or the viscous nature of a gel allows the conductive fluid to remain around the active and return electrodes for long enough to complete its function according to the present invention, as described below. Alternatively, the conductive fluid, such as a gel, may be applied directly to the target site.

In alternative embodiments, the fluid path may be formed in probe 90 by, for example, an inner lumen or an annular gap between the return electrode and a tubular support member within shaft 100 (see Figs. 8A and 8B). This annular gap may be formed near the perimeter of the shaft 100 such that the electrically conducting fluid tends to flow radially inward towards the target site, or it may be formed towards the center of shaft 100 so that the fluid flows radially outward. In both of these embodiments, a fluid source (e.g., a bag of fluid elevated above the surgical site or having a pumping device), is coupled to probe 90 via a fluid supply tube (not shown) that may or may not have a controllable valve. A more complete description of an electrosurgical probe incorporating one or more fluid lumen(s) can be found in U.S. Patent No. 5,697,281, the complete disclosure of which has previously been incorporated herein by reference.

Referring to Fig. 5, the electrically isolated electrode terminals 104 are spaced apart over tissue treatment surface 212 of electrode support member 102. The tissue treatment surface and individual electrode terminals 104 will usually have dimensions within the ranges set forth above. In the representative embodiment, the tissue treatment surface 212 has a circular cross-sectional shape with a diameter in the range of 1 mm to 20. The individual electrode terminals 104 preferably extend outward from tissue

treatment surface 212 by a distance of about 0.1 to 4 mm, usually about 0.2 to 2 mm.

Applicant has found that this configuration increases the high electric field intensities and associated current densities around electrode terminals 104 to facilitate the ablation of tissue as described in detail above.

5 In the embodiment of Figs. 4-6, the probe includes a single, larger opening 209 in the center of tissue treatment surface 212, and a plurality of electrode terminals (e.g., about 3-15) around the perimeter of surface 212 (see Fig. 5). Alternatively, the probe may include a single, annular, or partially annular, electrode terminal at the perimeter of the tissue treatment surface. The central opening 209 is coupled to a suction 10 lumen (not shown) within shaft 100 and a suction tube 211 (Fig. 4) for aspirating tissue, fluids and/or gases from the target site. In this embodiment, the electrically conductive fluid generally flows radially inward past electrode terminals 104 and then back through the opening 209. Aspirating the electrically conductive fluid during surgery allows the 15 surgeon to see the target site, and it prevents the fluid from flowing into the patient's body.

Of course, it will be recognized that the distal tip of probe may have a variety of different configurations. For example, the probe may include a plurality of openings 209 around the outer perimeter of tissue treatment surface 212 (see Fig. 7B). In this embodiment, the electrode terminals 104 extend distally from the center of tissue 20 treatment surface 212 such that they are located radially inward from openings 209. The openings are suitably coupled to fluid tube 233 for delivering electrically conductive fluid to the target site, and suction tube 211 for aspirating the fluid after it has completed the conductive path between the return electrode 112 and the electrode terminals 104.

Fig. 6 illustrates the electrical connections 250 within handle 204 for 25 coupling electrode terminals 104 and return electrode 112 to the power supply 28. As shown, a plurality of wires 252 extend through shaft 100 to couple terminals 104 to a plurality of pins 254, which are plugged into a connector block 256 for coupling to a connecting cable 22 (Fig. 1). Similarly, return electrode 112 is coupled to connector block 256 via a wire 258 and a plug 260.

According to the present invention, the probe 20 further includes an 30 identification element that is characteristic of the particular electrode assembly so that the same power supply 28 can be used for different electrosurgical operations. In one embodiment, for example, the probe 20 includes a voltage reduction element or a voltage

reduction circuit for reducing the voltage applied between the electrode terminals 104 and the return electrode 112. The voltage reduction element serves to reduce the voltage applied by the power supply so that the voltage between the electrode terminals and the return electrode is low enough to avoid excessive power dissipation into the electrically conducting medium and/or ablation of the soft tissue at the target site. In some embodiments, the voltage reduction element allows the power supply 28 to apply two different voltages simultaneously to two different electrodes (see Fig. 15D). In other embodiments, the voltage reduction element primarily allows the electrosurgical probe 90 to be compatible with other ArthroCare generators that are adapted to apply higher voltages for ablation or vaporization of tissue. For thermal heating or coagulation of tissue, for example, the voltage reduction element will serve to reduce a voltage of about 100 to 170 volts rms (which is a setting of 1 or 2 on the ArthroCare Model 970 and 980 (i.e., 2000) Generators) to about 45 to 60 volts rms, which is a suitable voltage for coagulation of tissue without ablation (e.g., molecular dissociation) of the tissue.

Of course, for some procedures, the probe will typically not require a voltage reduction element. Alternatively, the probe may include a voltage increasing element or circuit, if desired. Alternatively or additionally, the cable 22 that couples the power supply 10 to the probe 90 may be used as a voltage reduction element. The cable has an inherent capacitance that can be used to reduce the power supply voltage if the cable is placed into the electrical circuit between the power supply, the electrode terminals and the return electrode. In this embodiment, the cable 22 may be used alone, or in combination with one of the voltage reduction elements discussed above, e.g., a capacitor. Further, it should be noted that the present invention can be used with a power supply that is adapted to apply a voltage within the selected range for treatment of tissue. In this embodiment, a voltage reduction element or circuitry may not be desired.

Figs. 8A-8C schematically illustrate the distal portion of three different embodiments of probe 90 according to the present invention. As shown in 8A, electrode terminals 104 are anchored in a support matrix 102 of suitable insulating material (e.g., silicone or a ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure. The preferred support matrix material is alumina, available from Kyocera Industrial Ceramics Corporation, Elkgrove, Illinois, because of its high thermal conductivity, good electrically insulative properties, high

flexural modulus, resistance to carbon tracking, biocompatibility, and high melting point. The support matrix 102 is adhesively joined to a tubular support member 78 that extends most or all of the distance between matrix 102 and the proximal end of probe 90. Tubular member 78 preferably comprises an electrically insulating material, such as an epoxy or 5 silicone-based material.

In a preferred construction technique, electrode terminals 104 extend through pre-formed openings in the support matrix 102 so that they protrude above tissue treatment surface 212 by the desired distance. The electrodes are then bonded to the tissue treatment surface 212 of support matrix 102, typically by an inorganic sealing material 80. 10 Sealing material 80 is selected to provide effective electrical insulation, and good adhesion to both the alumina matrix 102 and the platinum or titanium electrode terminals. Sealing material 80 additionally should have a compatible thermal expansion coefficient and a melting point well below that of platinum or titanium and alumina or zirconia, typically being a glass or glass ceramic.

15 In the embodiment shown in Fig. 8A, return electrode 112 comprises an annular member positioned around the exterior of shaft 100 of probe 90. Return electrode 90 may fully or partially circumscribe tubular support member 78 to form an annular gap 54 therebetween for flow of electrically conducting liquid 50 therethrough, as discussed below. Gap 54 preferably has a width in the range of 0.25 mm to 4 mm. Alternatively, 20 probe may include a plurality of longitudinal ribs between support member 78 and return electrode 112 to form a plurality of fluid lumens extending along the perimeter of shaft 100. In this embodiment, the plurality of lumens will extend to a plurality of openings.

Return electrode 112 is disposed within an electrically insulative jacket 18, which is typically formed as one or more electrically insulative sheaths or coatings, such as 25 polytetrafluoroethylene, polyamide, and the like. The provision of the electrically insulative jacket 18 over return electrode 112 prevents direct electrical contact between return electrode 56 and any adjacent body structure. Such direct electrical contact between a body structure (*e.g.*, tendon) and an exposed electrode member 112 could result in unwanted heating and necrosis of the structure at the point of contact causing necrosis.

30 As shown in Fig. 8A, return electrode 112 is not directly connected to electrode terminals 104. To complete this current path so that terminals 104 are electrically connected to return electrode 112, electrically conducting liquid 50 (*e.g.*, isotonic saline) is caused to flow along fluid path(s) 83. Fluid path 83 is formed by

annular gap 54 between outer return electrode 112 and tubular support member. The electrically conducting liquid 50 flowing through fluid path 83 provides a pathway for electrical current flow between electrode terminals 104 and return electrode 112, as illustrated by the current flux lines 60 in Fig. 8A. When a voltage difference is applied 5 between electrode terminals 104 and return electrode 112, high electric field intensities will be generated at the distal tips of terminals 104 with current flow from terminals 104 through the target tissue to the return electrode, the high electric field intensities causing ablation of tissue 52 in zone 88.

Fig. 8B illustrates another alternative embodiment of electrosurgical probe 10 90 which has a return electrode 112 positioned within tubular member 78. Return electrode 112 is preferably a tubular member defining an inner lumen 57 for allowing electrically conducting liquid 50 (e.g., isotonic saline) to flow therethrough in electrical contact with return electrode 112. In this embodiment, a voltage difference is applied 15 between electrode terminals 104 and return electrode 112 resulting in electrical current flow through the electrically conducting liquid 50 as shown by current flux lines 60. As a result of the applied voltage difference and concomitant high electric field intensities at the tips of electrode terminals 104, tissue 52 becomes ablated or transected in zone 88.

Fig. 8C illustrates another embodiment of probe 90 that is a combination of the embodiments in Figs. 8A and 8B. As shown, this probe includes both an inner lumen 20 57 and an outer gap or plurality of outer lumens 54 for flow of electrically conductive fluid. In this embodiment, the return electrode 112 may be positioned within tubular member 78 as in Fig. 8B, outside of tubular member 78 as in Fig. 8A, or in both locations.

In some embodiments, the probe 20 will also include one or more aspiration 25 electrode(s) coupled to the aspiration lumen for inhibiting clogging during aspiration of tissue fragments from the surgical site. As shown in Fig. 9, one or more of the active electrode terminals 104 may comprise loop electrodes 140 that extend across distal opening 209 of the suction lumen within shaft 100. In the representative embodiment, two of the electrode terminals 104 comprise loop electrodes 140 that cross over the distal opening 30 209. Of course, it will be recognized that a variety of different configurations are possible, such as a single loop electrode, or multiple loop electrodes having different configurations than shown. In addition, the electrodes may have shapes other than loops, such as the coiled configurations shown in Figs. 10 and 11. Alternatively, the electrodes

may be formed within suction lumen proximal to the distal opening 209, as shown in Fig. 13. The main function of loop electrodes 140 is to ablate portions of tissue that are drawn into the suction lumen to prevent clogging of the lumen.

In some embodiments, loop electrodes 140 are electrically isolated from the other electrode terminals 104, which can be referred to hereinafter as the ablation electrodes 104. In other embodiments, the loop electrodes 140 and electrode terminals 104 may be electrically connected to each other such that both are activated together. Loop electrodes 140 may or may not be electrically isolated from each other. Loop electrodes 140 will usually extend only about 0.05 to 4 mm, preferably about 0.1 to 1 mm from the tissue treatment surface of electrode support member 104.

Referring now to Figs. 10 and 11, alternative embodiments for aspiration electrodes will now be described. As shown in Fig. 10, the aspiration electrodes may comprise a pair of coiled electrodes 150 that extend across distal opening 209 of the suction lumen. The larger surface area of the coiled electrodes 150 usually increases the effectiveness of the electrodes 150 on tissue fragments passing through opening 209. In Fig. 11, the aspiration electrode comprises a single coiled electrode 152 passing across the distal opening 209 of suction lumen. This single electrode 152 may be sufficient to inhibit clogging of the suction lumen. Alternatively, the aspiration electrodes may be positioned within the suction lumen proximal to the distal opening 209. Preferably, these electrodes are close to opening 209 so that tissue does not clog the opening 209 before it reaches electrodes 154. In this embodiment, a separate return electrode 156 may be provided within the suction lumen to confine the electric currents therein.

Referring to Fig. 13, another embodiment of the present invention incorporates an aspiration electrode 160 within the aspiration lumen 162 of the probe. As shown, the electrode 160 is positioned just proximal of distal opening 209 so that the tissue fragments are ablated as they enter lumen 162. In the representation embodiment, the aspiration electrode 160 comprises a loop electrode that stretches across the aspiration lumen 162. However, it will be recognized that many other configurations are possible. In this embodiment, the return electrode 164 is located outside of the probe as in the previously embodiments. Alternatively, the return electrode(s) may be located within the aspiration lumen 162 with the aspiration electrode 160. For example, the inner insulating coating 163 may be exposed at portions within the lumen 162 to provide a conductive path between this exposed portion of return electrode 164 and the aspiration electrode 160. The

latter embodiment has the advantage of confining the electric currents to within the aspiration lumen. In addition, in dry fields in which the conductive fluid is delivered to the target site, it is usually easier to maintain a conductive fluid path between the active and return electrodes in the latter embodiment because the conductive fluid is aspirated through the aspiration lumen 162 along with the tissue fragments.

Referring to Fig. 12, another embodiment of the present invention incorporates a wire mesh electrode 600 extending across the distal portion of aspiration lumen 162. As shown, mesh electrode 600 includes a plurality of openings 602 to allow fluids and tissue fragments to flow through into aspiration lumen 162. The size of the openings 602 will vary depending on a variety of factors. The mesh electrode may be coupled to the distal or proximal surfaces of ceramic support member 102. Wire mesh electrode 600 comprises a conductive material, such as titanium, tantalum, steel, stainless steel, tungsten, copper, gold or the like. In the representative embodiment, wire mesh electrode 600 comprises a different material having a different electric potential than the active electrode terminal(s) 104. Preferably, mesh electrode 600 comprises steel and electrode terminal(s) comprises tungsten. Applicant has found that a slight variance in the electrochemical potential of mesh electrode 600 and electrode terminal(s) 104 improves the performance of the device. Of course, it will be recognized that the mesh electrode may be electrically insulated from active electrode terminal(s) as in previous embodiments

Referring now to Figs. 14A-14C, an alternative embodiment incorporating a metal screen 610 is illustrated. As shown, metal screen 610 has a plurality of peripheral openings 612 for receiving electrode terminals 104, and a plurality of inner openings 614 for allowing aspiration of fluid and tissue through opening 609 of the aspiration lumen. As shown, screen 610 is press fitted over electrode terminals 104 and then adhered to shaft 100 of probe 20. Similar to the mesh electrode embodiment, metal screen 610 may comprise a variety of conductive metals, such as titanium, tantalum, steel, stainless steel, tungsten, copper, gold or the like. In the representative embodiment, metal screen 610 is coupled directly to, or integral with, active electrode terminal(s) 104. In this embodiment, the active electrode terminal(s) 104 and the metal screen 610 are electrically coupled to each other.

Figs. 15A -15D illustrate embodiments of an electrosurgical probe 350 specifically designed for the treatment of herniated or diseased spinal discs. Referring to Fig. 15A, probe 350 comprises an electrically conductive shaft 352, a handle 354 coupled

to the proximal end of shaft 352 and an electrically insulating support member 356 at the distal end of shaft 352. Probe 350 further includes a shrink wrapped insulating sleeve 358 over shaft 352, and exposed portion of shaft 352 that functions as the return electrode 360.

In the representative embodiment, probe 350 comprises a plurality of active electrodes

5 362 extending from the distal end of support member 356. As shown, return electrode 360 is spaced a further distance from active electrodes 362 than in the embodiments described above. In this embodiment, the return electrode 360 is spaced a distance of about 2.0 to 50 mm, preferably about 5 to 25 mm. In addition, return electrode 360 has a larger exposed surface area than in previous embodiments, having a length in the range of about 10 2.0 to 40 mm, preferably about 5 to 20 mm. Accordingly, electric current passing from active electrodes 362 to return electrode 360 will follow a current flow path 370 that is further away from shaft 352 than in the previous embodiments. In some applications, this current flow path 370 results in a deeper current penetration into the surrounding tissue with the same voltage level, and thus increased thermal heating of the tissue. As discussed 15 above, this increased thermal heating may have advantages in some applications of treating disc abnormalities. Typically, it is desired to achieve a tissue temperature in the range of about 60°C to 100°C to a depth of about 0.2 to 5 mm, usually about 1 to 2 mm. The voltage required for this thermal damage will partly depend on the electrode configurations, the conductivity of the tissue and the area immediately surrounding the 20 electrodes, the time period in which the voltage is applied and the depth of tissue damage desired. With the electrode configurations described in Figs. 15A-15D, the voltage level for thermal heating will usually be in the range of about 20 to 300 volts rms, preferably about 60 to 200 volts rms. The peak-to-peak voltages for thermal heating with a square wave form having a crest factor of about 2 are typically in the range of about 40 to 600 25 volts peak-to-peak, preferably about 120 to 400 volts peak-to-peak. The higher the voltage is within this range, the less time required. If the voltage is too high, however, the surface tissue may be vaporized, debulked or ablated, which is undesirable.

In alternative embodiments, the electrosurgical system used in conjunction with probe 350 may include a dispersive return electrode 450 (see Fig. 16) for switching 30 between bipolar and monopolar modes. In this embodiment, the system will switch between an ablation mode, where the dispersive pad 450 is deactivated and voltage is applied between active and return electrodes 362, 360, and a subablation or thermal heating mode, where the active electrode(s) 362 and deactivated and voltage is applied

between the dispersive pad 450 and the return electrode 360. In the subablation mode, a lower voltage is typically applied and the return electrode 360 functions as the active electrode to provide thermal heating and/or coagulation of tissue surrounding return electrode 360.

5 Fig. 15B illustrates yet another embodiment of the present invention. As shown, electrosurgical probe 350 comprises an electrode assembly 372 having one or more active electrode(s) 362 and a proximally spaced return electrode 360 as in previous embodiments. Return electrode 360 is typically spaced about 0.5 to 25 mm, preferably 1.0 to 5.0 mm from the active electrode(s) 362, and has an exposed length of about 1 to 20
10 mm. In addition, electrode assembly 372 includes two additional electrodes 374, 376 spaced axially on either side of return electrode 360. Electrodes 374, 376 are typically spaced about 0.5 to 25 mm, preferably about 1 to 5 mm from return electrode 360. In the representative embodiment, the additional electrodes 374, 376 are exposed portions of shaft 352, and the return electrode 360 is electrically insulated from shaft 352 such that a
15 voltage difference may be applied between electrodes 374, 376 and electrode 360. In this embodiment, probe 350 may be used in at least two different modes, an ablation mode and a subablation or thermal heating mode. In the ablation mode, voltage is applied between active electrode(s) 362 and return electrode 360 in the presence of electrically conductive fluid, as described above. In the ablation mode, electrodes 374, 376 are deactivated. In
20 the thermal heating or coagulation mode, active electrode(s) 362 are deactivated and a voltage difference is applied between electrodes 374, 376 and electrode 360 such that a high frequency current 370 flows therebetween, as shown in Fig. 15B. In the thermal heating mode, a lower voltage is typically applied below the threshold for plasma formation and ablation, but sufficient to cause some thermal damage to the tissue
25 immediately surrounding the electrodes without vaporizing or otherwise debulking this tissue so that the current 370 provides thermal heating and/or coagulation of tissue surrounding electrodes 360, 372, 374.

Fig. 15C illustrates another embodiment of probe 350 incorporating an electrode assembly 372 having one or more active electrode(s) 362 and a proximally spaced return electrode 360 as in previous embodiments. Return electrode 360 is typically spaced about 0.5 to 25 mm, preferably 1.0 to 5.0 mm from the active electrode(s) 362, and has an exposed length of about 1 to 20 mm. In addition, electrode assembly 372 includes a second active electrode 380 separated from return electrode 360 by an electrically

insulating spacer 382. In this embodiment, handle 354 includes a switch 384 for toggling probe 350 between at least two different modes, an ablation mode and a subablation or thermal heating mode. In the ablation mode, voltage is applied between active electrode(s) 362 and return electrode 360 in the presence of electrically conductive fluid, as described above. In the ablation mode, electrode 380 deactivated. In the thermal heating or coagulation mode, active electrode(s) 362 may be deactivated and a voltage difference is applied between electrode 380 and electrode 360 such that a high frequency current 370 flows therebetween. Alternatively, active electrode(s) 362 may not be deactivated as the higher resistance of the smaller electrodes may automatically send the electric current to electrode 380 without having to physically decouple electrode(s) 362 from the circuit. In the thermal heating mode, a lower voltage is typically applied below the threshold for plasma formation and ablation, but sufficient to cause some thermal damage to the tissue immediately surrounding the electrodes without vaporizing or otherwise debulking this tissue so that the current 370 provides thermal heating and/or coagulation of tissue surrounding electrodes 360, 380.

Of course, it will be recognized that a variety of other embodiments may be used to accomplish similar functions as the embodiments described above. For example, electrosurgical probe 350 may include a plurality of helical bands formed around shaft 352, with one or more of the helical bands having an electrode coupled to the portion of the band such that one or more electrodes are formed on shaft 352 spaced axially from each other.

Fig. 15D illustrates another embodiment of the invention designed for channeling through tissue and creating lesions therein to treat spinal discs and/or snoring and sleep apnea. As shown, probe 350 is similar to the probe in Fig. 15C having a return electrode 360 and a third, coagulation electrode 380 spaced proximally from the return electrode 360. In this embodiment, active electrode 362 comprises a single electrode wire extending distally from insulating support member 356. Of course, the active electrode 362 may have a variety of configurations to increase the current densities on its surfaces, e.g., a conical shape tapering to a distal point, a hollow cylinder, loop electrode and the like. In the representative embodiment, support members 356 and 382 are constructed of inorganic material, such as ceramic, glass, silicone and the like. The proximal support member 382 may also comprise a more conventional organic material as this support

member 382 will generally not be in the presence of a plasma that would otherwise etch or wear away an organic material.

The probe 350 in Fig. 15D does not include a switching element. In this embodiment, all three electrodes are activated when the power supply is activated. The 5 return electrode 360 has an opposite polarity from the active and coagulation electrodes 362, 380 such that current 370 flows from the latter electrodes to the return electrode 360 as shown. In the preferred embodiment, the electrosurgical system includes a voltage reduction element or a voltage reduction circuit for reducing the voltage applied between the coagulation electrode 380 and return electrode 360. The voltage reduction element 10 allows the power supply 28 to, in effect, apply two different voltages simultaneously to two different electrodes. Thus, for channeling through tissue, the operator may apply a voltage sufficient to provide ablation of the tissue at the tip of the probe (i.e., tissue adjacent to the active electrode 362). At the same time, the voltage applied to the coagulation electrode 380 will be insufficient to ablate tissue. For thermal heating or 15 coagulation of tissue, for example, the voltage reduction element will serve to reduce a voltage of about 100 to 300 volts rms to about 45 to 90 volts rms, which is a suitable voltage for coagulation of tissue without ablation (e.g., molecular dissociation) of the tissue.

In the representative embodiment, the voltage reduction element is a 20 capacitor (not shown) coupled to the power supply and coagulation electrode 380. The capacitor usually has a capacitance of about 200 to 500 pF (at 500 volts) and preferably about 300 to 350 pF (at 500 volts). Of course, the capacitor may be located in other places within the system, such as in, or distributed along the length of, the cable, the generator, the connector, etc. In addition, it will be recognized that other voltage reduction elements, 25 such as diodes, transistors, inductors, resistors, capacitors or combinations thereof, may be used in conjunction with the present invention. For example, the probe 350 may include a coded resistor (not shown) that is constructed to lower the voltage applied between the return and coagulation electrodes 360, 380. In addition, electrical circuits may be employed for this purpose.

30 Of course, for some procedures, the probe will typically not require a voltage reduction element. Alternatively, the probe may include a voltage increasing element or circuit, if desired. Alternatively or additionally, the cable 22 that couples the power supply 10 to the probe 90 may be used as a voltage reduction element. The cable

has an inherent capacitance that can be used to reduce the power supply voltage if the cable is placed into the electrical circuit between the power supply, the electrode terminals and the return electrode. In this embodiment, the cable 22 may be used alone, or in combination with one of the voltage reduction elements discussed above, e.g., a capacitor.

5 Further, it should be noted that the present invention can be used with a power supply that is adapted to apply two different voltages within the selected range for treatment of tissue. In this embodiment, a voltage reduction element or circuitry may not be desired.

In one specific embodiment, the probe 350 is manufactured by first inserting an electrode wire (active electrode 362) through a ceramic tube (insulating member 360) such that a distal portion of the wire extends through the distal portion of the tube, and bonding the wire to the tube, typically with an appropriate epoxy. A stainless steel tube (return electrode 356) is then placed over the proximal portion of the ceramic tube, and a wire (e.g., nickel wire) is bonded, typically by spot welding, to the inside surface of the stainless steel tube. The stainless steel tube is coupled to the ceramic tube by epoxy, and 10 the device is cured in an oven or other suitable heat source. A second ceramic tube (insulating member 382) is then placed inside of the proximal portion of the stainless steel tube, and bonded in a similar manner. The shaft 358 is then bonded to the proximal portion of the second ceramic tube, and an insulating sleeve (e.g. polyimide) is wrapped around shaft 358 such that only a distal portion of the shaft is exposed (i.e., coagulation 15 electrode 380). The nickel wire connection will extend through the center of shaft 358 to connect return electrode 356 to the power supply. The active electrode 362 may form a distal portion of shaft 358, or it may also have a connector extending through shaft 358 to the power supply.

20

In use, the physician positions active electrode 362 adjacent to the tissue 25 surface to be treated (i.e., a spinal disc). The power supply is activated to provide an ablation voltage between active and return electrodes 362, 360 and a coagulation or thermal heating voltage between coagulation and return electrodes 360, 380. An electrically conductive fluid is then provided around active electrode 362, and in the junction between the active and return electrodes 360, 362 to provide a current flow path 30 therebetween. This may be accomplished in a variety of manners, as discussed above. The active electrode 362 is then advanced through the space left by the ablated tissue to form a channel in the disc. During ablation, the electric current between the coagulation and return electrode is typically insufficient to cause any damage to the surface of the

tissue as these electrodes pass through the tissue surface into the channel created by active electrode 362. Once the physician has formed the channel to the appropriate depth, he or she will cease advancement of the active electrode, and will either hold the instrument in place for 5 to 30 seconds, or will immediately remove the distal tip of the instrument from 5 the channel (see detailed discussion of this below). In either event, when the active electrode is no longer advancing, it will eventually stop ablating tissue.

Prior to entering the channel formed by the active electrode 362, an open circuit exists between return and coagulation electrodes 360, 380. Once coagulation electrode 380 enters this channel, electric current will flow from coagulation electrode 10 380, through the tissue surrounding the channel, to return electrode 360. This electric current will heat the tissue immediately surrounding the channel to coagulate any severed vessels at the surface of the channel. If the physician desires, the instrument may be held within the channel for a period of time to create a lesion around the channel, as discussed in more detail below.

Fig. 16 illustrates yet another embodiment of an electrosurgical system 440 incorporating a dispersive return pad 450 attached to the electrosurgical probe 400. In this embodiment, the invention functions in the bipolar mode as described above. In addition, the system 440 may function in a monopolar mode in which a high frequency voltage difference is applied between the active electrode(s) 410, and the dispersive return pad 20 450. In the exemplary embodiment, the pad 450 and the probe 400 are coupled together, and are both disposable, single-use items. The pad 450 includes an electrical connector 452 that extends into handle 404 of probe 400 for direct connection to the power supply. Of course, the invention would also be operable with a standard return pad that connects directly to the power supply. In this embodiment, the power supply 460 will include a 25 switch, e.g., a foot pedal 462, for switching between the monopolar and bipolar modes. In the bipolar mode, the return path on the power supply is coupled to return electrode 408 on probe 400, as described above. In the monopolar mode, the return path on the power supply is coupled to connector 452 of pad 450, active electrode(s) 410 are decoupled from the electrical circuit, and return electrode 408 functions as the active electrode. This allows the surgeon to switch between bipolar and monopolar modes during, or prior to, the 30 surgical. In some cases, it may be desirable to operate in the monopolar mode to provide deeper current penetration and, thus, a greater thermal heating of the tissue surrounding

the return electrodes. In other cases, such as ablation of tissue, the bipolar modality may be preferable to limit the current penetration to the tissue.

In one configuration, the dispersive return pad 450 is adapted for coupling to an external surface of the patient in a region substantially close to the target region. For example, during the treatment of tissue in the head and neck, the dispersive return pad is designed and constructed for placement in or around the patient's shoulder, upper back or upper chest region. This design limits the current path through the patient's body to the head and neck area, which minimizes the damage that may be generated by unwanted current paths in the patient's body, particularly by limiting current flow through the patient's heart. The return pad is also designed to minimize the current densities at the pad, to thereby minimize patient skin burns in the region where the pad is attached.

Referring to Fig. 17, the electrosurgical device according to the present invention may also be configured as a catheter system 400. As shown in Fig. 17, a catheter system 400 generally comprises an electrosurgical catheter 460 connected to a power supply 28 by an interconnecting cable 486 for providing high frequency voltage to a target tissue and an irrigant reservoir or source 600 for providing electrically conducting fluid to the target site. Catheter 460 generally comprises an elongate, flexible shaft body 462 including a tissue removing or ablating region 464 at the distal end of body 462. The proximal portion of catheter 460 includes a multi-lumen fitment 614 which provides for interconnections between lumens and electrical leads within catheter 460 and conduits and cables proximal to fitment 614. By way of example, a catheter electrical connector 496 is removably connected to a distal cable connector 494 which, in turn, is removably connectable to generator 28 through connector 492. One or more electrically conducting lead wires (not shown) within catheter 460 extend between one or more active electrodes 463 and a coagulation electrode 467 at tissue ablating region 464 and one or more corresponding electrical terminals (also not shown) in catheter connector 496 via active electrode cable branch 487. Similarly, a return electrode 466 at tissue ablating region 464 are coupled to a return electrode cable branch 489 of catheter connector 496 by lead wires (not shown). Of course, a single cable branch (not shown) may be used for both active and return electrodes.

Catheter body 462 may include reinforcing fibers or braids (not shown) in the walls of at least the distal ablation region 464 of body 462 to provide responsive torque control for rotation of electrode terminals during tissue engagement. This rigid portion of

the catheter body 462 preferably extends only about 7 to 10 mm while the remainder of the catheter body 462 is flexible to provide good trackability during advancement and positioning of the electrodes adjacent target tissue.

Conductive fluid 30 is provided to tissue ablation region 464 of catheter 460 via a lumen (not shown in Fig. 17) within catheter 460. Fluid is supplied to lumen from the source along a conductive fluid supply line 602 and a conduit 603, which is coupled to the inner catheter lumen at multi-lumen fitment 114. The source of conductive fluid (e.g., isotonic saline) may be an irrigant pump system (not shown) or a gravity-driven supply, such as an irrigant reservoir 600 positioned several feet above the level of the patient and tissue ablating region 8. A control valve 604 may be positioned at the interface of fluid supply line 602 and conduit 603 to allow manual control of the flow rate of electrically conductive fluid 30. Alternatively, a metering pump or flow regulator may be used to precisely control the flow rate of the conductive fluid.

System 400 further includes an aspiration or vacuum system (not shown) to aspirate liquids and gases from the target site. The aspiration system will usually comprise a source of vacuum coupled to fitment 614 by a aspiration connector 605.

The present invention is particularly useful in microendoscopic discectomy procedures, e.g., for decompressing a nerve root with a lumbar discectomy. As shown in Figs. 18-23, a percutaneous penetration 270 is made in the patients' back 272 so that the superior lamina 274 can be accessed. Typically, a small needle (not shown) is used initially to localize the disc space level, and a guidewire (not shown) is inserted and advanced under lateral fluoroscopy to the inferior edge of the lamina 274. Sequential cannulated dilators 276 are inserted over the guide wire and each other to provide a hole from the incision 220 to the lamina 274. The first dilator may be used to "palpate" the lamina 274, assuring proper location of its tip between the spinous process and facet complex just above the inferior edge of the lamina 274. As shown in Fig. 21, a tubular retractor 278 is then passed over the largest dilator down to the lamina 274. The dilators 276 are removed, establishing an operating corridor within the tubular retractor 278.

As shown in Fig. 19, an endoscope 280 is then inserted into the tubular retractor 278 and a ring clamp 282 is used to secure the endoscope 280. Typically, the formation of the operating corridor within retractor 278 requires the removal of soft tissue, muscle or other types of tissue that were forced into this corridor as the dilators 276 and retractor 278 were advanced down to the lamina 274. This tissue is usually removed with

mechanical instruments, such as pituitary rongeurs, curettes, graspers, cutters, drills, microdebriders and the like. Unfortunately, these mechanical instruments greatly lengthen and increase the complexity of the procedure. In addition, these instruments sever blood vessels within this tissue, usually causing profuse bleeding that obstructs the surgeon's
5 view of the target site.

According to one aspect of the present invention, an electrosurgical probe or catheter 284 as described above is introduced into the operating corridor within the retractor 278 to remove the soft tissue, muscle and other obstructions from this corridor so that the surgeon can easily access and visualization the lamina 274. Once the surgeon has
10 reached has introduced the probe 284, electrically conductive fluid 285 is delivered through tube 233 and opening 237 to the tissue (see Fig. 2). The fluid flows past the return electrode 112 to the electrode terminals 104 at the distal end of the shaft. The rate of fluid flow is controlled with valve 17 (Fig. 1) such that the zone between the tissue and electrode support 102 is constantly immersed in the fluid. The power supply 28 is then
15 turned on and adjusted such that a high frequency voltage difference is applied between electrode terminals 104 and return electrode 112. The electrically conductive fluid provides the conduction path (see current flux lines) between electrode terminals 104 and the return electrode 112.

The high frequency voltage is sufficient to convert the electrically
20 conductive fluid (not shown) between the target tissue and electrode terminal(s)104 into an ionized vapor layer or plasma (not shown). As a result of the applied voltage difference between electrode terminal(s) 104 and the target tissue (i.e., the voltage gradient across the plasma layer), charged particles in the plasma (viz., electrons) are accelerated towards the tissue. At sufficiently high voltage differences, these charged particles gain sufficient
25 energy to cause dissociation of the molecular bonds within tissue structures. This molecular dissociation is accompanied by the volumetric removal (i.e., ablative sublimation) of tissue and the production of low molecular weight gases, such as oxygen, nitrogen, carbon dioxide, hydrogen and methane. The short range of the accelerated charged particles within the tissue confines the molecular dissociation process to the
30 surface layer to minimize damage and necrosis to the underlying tissue.

During the process, the gases will be aspirated through opening 209 and suction tube 211 to a vacuum source. In addition, excess electrically conductive fluid, and other fluids (e.g., blood) will be aspirated from the operating corridor to facilitate the

surgeon's view. During ablation of the tissue, the residual heat generated by the current flux lines (typically less than 150°C), will usually be sufficient to coagulate any severed blood vessels at the site. If not, the surgeon may switch the power supply 28 into the coagulation mode by lowering the voltage to a level below the threshold for fluid vaporization, as discussed above. This simultaneous hemostasis results in less bleeding and facilitates the surgeon's ability to perform the procedure.

Another advantage of the present invention is the ability to precisely ablate soft tissue without causing necrosis or thermal damage to the underlying and surrounding tissues, nerves or bone. In addition, the voltage can be controlled so that the energy directed to the target site is insufficient to ablate the lamina 274 so that the surgeon can literally clean the tissue off the lamina 274, without ablating or otherwise effecting significant damage to the lamina.

Referring now to Figs. 20 and 21, once the operating corridor is sufficiently cleared, a laminotomy and medial facetectomy is accomplished either with conventional techniques (e.g., Kerrison punch or a high speed drill) or with the electrosurgical probe 284 as discussed above. After the nerve root is identified, medical retraction can be achieved with a retractor 288, or the present invention can be used to precisely ablate the disc. If necessary, epidural veins are cauterized either automatically or with the coagulation mode of the present invention. If an annulotomy is necessary, it can be accomplished with a microknife or the ablation mechanism of the present invention while protecting the nerve root with the retractor 288. The herniated disc 290 is then removed with a pituitary rongeur in a standard fashion, or once again through ablation as described above.

In another embodiment, the present invention involves a channeling technique in which small holes or channels are formed within the disc 290, and thermal energy is applied to the tissue surface immediately surrounding these holes or channels to cause thermal damage to the tissue surface, thereby stiffening and debulking the surrounding tissue structure of the disc. Applicant has discovered that such stiffening of the tissue structure in the disc helps to reduce the pressure applied against the spinal nerves by the disc, thereby relieving back and neck pain.

As shown in Fig. 21, the electrosurgical instrument 350 is introduced to the target site at the disc 290 as described above, or in another percutaneous manner (see Figs. 23-25 below). The electrode assembly 351 is positioned adjacent to or against the disc

surface, and electrically conductive fluid is delivered to the target site, as described above.

Alternatively, the conductive fluid is applied to the target site, or the distal end of probe 350 is dipped into conductive fluid or gel prior to introducing the probe 350 into the patient. The power supply 28 is then activated and adjusted such that a high frequency voltage difference is applied to the electrode assembly as described above.

Depending on the procedure, the surgeon may translate the electrodes relative to the target disc tissue to form holes, channels, stripes, divots, craters or the like within the disc. In addition, the surgeon may purposely create some thermal damage within these holes, or channels to form scar tissue that will stiffen and debulk the disc. In

one embodiment, the physician axially translates the electrode assembly 351 into the disc tissue as the tissue is volumetrically removed to form one or more holes 702 therein (see also Fig. 22). The holes 702 will typically have a diameter of less than 2 mm, preferably less than 1 mm. In another embodiment (not shown), the physician translates the active electrode across the outer surface of the disc to form one or more channels or troughs.

Applicant has found that the present invention can quickly and cleanly create such holes, divots or channels in tissue with the cold ablation technology described herein. A more complete description of methods for forming holes or channels in tissue can be found in U.S. Patent No. 5,683,366, the complete disclosure of which is incorporated herein by reference for all purposes.

Fig. 22 is a more detailed viewed of the probe 350 of Fig. 15D forming a hole 702 in a disc 290. Hole 702 is preferably formed with the methods described in detail above. Namely, a high frequency voltage difference is applied between active and return electrodes 362, 360, respectively, in the presence of an electrically conductive fluid such that an electric current 361 passes from the active electrode 362, through the conductive fluid, to the return electrode 360. As shown in Fig. 22, this will result in shallow or no current penetration into the disc tissue 704. The fluid may be delivered to the target site, applied directly to the target site, or the distal end of the probe may be dipped into the fluid prior to the procedure. The voltage is sufficient to vaporize the fluid around active electrode 362 to form a plasma with sufficient energy to effect molecular dissociation of the tissue. The distal end of the probe 350 is then axially advanced through the tissue as the tissue is removed by the plasma in front of the probe 350. The holes 702 will typically have a depth D in the range of about 0.5 to 2.5 cm, preferably about 1.2 to 1.8 cm, and a

diameter d of about 0.5 to 5 mm, preferably about 1.0 to 3.0 mm. The exact diameter will, of course, depend on the diameter of the electrosurgical probe used for the procedure.

During the formation of each hole 702, the conductive fluid between active and return electrodes 362, 360 will generally minimize current flow into the surrounding

5 tissue, thereby minimizing thermal damage to the tissue. Therefore, severed blood vessels on the surface 705 of the hole 702 may not be coagulated as the electrodes 362 advance through the tissue. In addition, in some procedures, it may be desired to thermally damage the surface 705 of the hole 702 to stiffen the tissue. For these reasons, it may be desired in some procedures to increase the thermal damage caused to the tissue surrounding hole

10 702. In the embodiment shown in Fig. 15D, it may be necessary to either: (1) withdraw the probe 350 slowly from hole 702 after coagulation electrode 380 has at least partially advanced past the outer surface of the disc tissue 704 into the hole 702 (as shown in Fig. 22); or (2) hold the probe 350 within the hole 702 for a period of time, e.g., on the order of 1 to 30 seconds. Once the coagulation electrode is in contact with, or adjacent to,

15 tissue, electric current 755 flows through the tissue surrounding hole 702 and creates thermal damage therein. The coagulation and return electrodes 380, 360 both have relatively large, smooth exposed surfaces to minimize high current densities at their surfaces, which minimizes damage to the surface 705 of hole. Meanwhile, the size and spacing of these electrodes 360, 380 allows for relatively deep current penetration into the

20 tissue 704. In the representative embodiment, the thermal necrosis 706 will extend about 1.0 to 5.0 mm from surface 705 of hole 702. In this embodiment, the probe may include one or more temperature sensors (not shown) on probe coupled to one or more temperature displays on the power supply 28 such that the physician is aware of the temperature within the hole 702 during the procedure.

25 In other embodiments, the physician switches the electrosurgical system from the ablation mode to the subablation or thermal heating mode after the hole 702 has been formed. This is typically accomplished by pressing a switch or foot pedal to reduce the voltage applied to a level below the threshold required for ablation for the particular electrode configuration and the conductive fluid being used in the procedure (as described

30 above). In the subablation mode, the physician will then remove the distal end of the probe 350 from the hole 702. As the probe is withdrawn, high frequency current flows from the active electrodes 362 through the surrounding tissue to the return electrode 360. This current flow heats the tissue and coagulates severed blood vessels at surface 704.

In another embodiment, the electrosurgical probe of the present invention can be used to ablate and/or contract soft tissue within the disc 290 to allow the annulus 292 to repair itself to prevent reoccurrence of this procedure. For tissue contraction, a sufficient voltage difference is applied between the electrode terminals 104 and the return electrode 112 to elevate the tissue temperature from normal body temperatures (e.g., 5 37°C) to temperatures in the range of 45°C to 90°C, preferably in the range from 60°C to 70°C. This temperature elevation causes contraction of the collagen connective fibers within the disc tissue so that the disc 290 withdraws into the annulus 292.

In one method of tissue contraction according to the present invention, an 10 electrically conductive fluid is delivered to the target site as described above, and heated to a sufficient temperature to induce contraction or shrinkage of the collagen fibers in the target tissue. The electrically conducting fluid is heated to a temperature sufficient to substantially irreversibly contract the collagen fibers, which generally requires a tissue 15 temperature in the range of about 45°C to 90°C, usually about 60°C to 70°C. The fluid is heated by applying high frequency electrical energy to the electrode terminal(s) in contact with the electrically conducting fluid. The current emanating from the electrode terminal(s) 104 heats the fluid and generates a jet or plume of heated fluid, which is directed towards the target tissue. The heated fluid elevates the temperature of the collagen sufficiently to cause hydrothermal shrinkage of the collagen fibers. The return 20 electrode 112 draws the electric current away from the tissue site to limit the depth of penetration of the current into the tissue, thereby inhibiting molecular dissociation and breakdown of the collagen tissue and minimizing or completely avoiding damage to surrounding and underlying tissue structures beyond the target tissue site. In an exemplary 25 embodiment, the electrode terminal(s) 104 are held away from the tissue a sufficient distance such that the RF current does not pass into the tissue at all, but rather passes through the electrically conducting fluid back to the return electrode. In this embodiment, the primary mechanism for imparting energy to the tissue is the heated fluid, rather than the electric current.

In an alternative embodiment, the electrode terminal(s) 104 are brought into 30 contact with, or close proximity to, the target tissue so that the electric current passes directly into the tissue to a selected depth. In this embodiment, the return electrode draws the electric current away from the tissue site to limit its depth of penetration into the tissue. Applicant has discovered that the depth of current penetration also can be varied with the

electrosurgical system of the present invention by changing the frequency of the voltage applied to the electrode terminal and the return electrode. This is because the electrical impedance of tissue is known to decrease with increasing frequency due to the electrical properties of cell membranes which surround electrically conductive cellular fluid. At 5 lower frequencies (e.g., less than 350 kHz), the higher tissue impedance, the presence of the return electrode and the electrode terminal configuration of the present invention (discussed in detail below) cause the current flux lines to penetrate less deeply resulting in a smaller depth of tissue heating. In an exemplary embodiment, an operating frequency of about 100 to 200 kHz is applied to the electrode terminal(s) to obtain shallow depths of 10 collagen shrinkage (e.g., usually less than 1.5 mm and preferably less than 0.5 mm).

In another aspect of the invention, the size (e.g., diameter or principal dimension) of the electrode terminals employed for treating the tissue are selected according to the intended depth of tissue treatment. As described previously in copending patent application PCT International Application, U.S. National Phase Serial No.

15 PCT/US94/05168, the depth of current penetration into tissue increases with increasing dimensions of an individual active electrode (assuming other factors remain constant, such as the frequency of the electric current, the return electrode configuration, etc.). The depth of current penetration (which refers to the depth at which the current density is sufficient to effect a change in the tissue, such as collagen shrinkage, irreversible necrosis, 20 etc.) is on the order of the active electrode diameter for the bipolar configuration of the present invention and operating at a frequency of about 100kHz to about 200kHz. Accordingly, for applications requiring a smaller depth of current penetration, one or more electrode terminals of smaller dimensions would be selected. Conversely, for applications 25 requiring a greater depth of current penetration, one or more electrode terminals of larger dimensions would be selected.

Figs. 23-25 illustrate another system and method for treating swollen or herniated spinal discs according to the present invention. In this procedure, an electrosurgical probe 700 comprises a long, thin needle-like shaft 702 (e.g., on the order of about 1 mm in diameter or less) that can be percutaneously introduced anteriorly 30 through the abdomen or thorax, or through the patient's back directly into the spine. The shaft 702 may or may not be flexible, depending on the method of access chosen by the physician. The probe shaft 702 will include one or more active electrode(s) 704 for applying electrical energy to tissues within the spine. The probe 700 may include one or

more return electrode(s) 706, or the return electrode may be positioned on the patient's back, as a dispersive pad (not shown). As discussed below, however, a bipolar design is preferable.

As shown in Fig. 23, the distal portion of shaft 702 is introduced anteriorly through a small percutaneous penetration into the annulus 710 of the target spinal disc. To facilitate this process, the distal end of shaft 702 may taper down to a sharper point (e.g., a needle), which can then be retracted to expose active electrode(s) 704. Alternatively, the electrodes may be formed around the surface of the tapered distal portion of shaft (not shown). In either embodiment, the distal end of shaft is delivered through the annulus 710 to the target nucleus pulposis 290, which may be herniated, extruded, non-extruded, or simply swollen. As shown in Fig. 24, high frequency voltage is applied between active electrode(s) 704 and return electrode(s) 710 to heat the surrounding collagen to suitable temperatures for contraction (i.e., typically about 55°C to about 70°C). As discussed above, this procedure may be accomplished with a monopolar configuration, as well. However, applicant has found that the bipolar configuration shown in Figs. 23-25 provides enhanced control of the high frequency current, which reduces the risk of spinal nerve damage.

As shown in Fig. 24 and 25, once the pulposis 290 has been sufficient contracted to retract from impingement on the nerve 720, the probe 700 is removed from the target site. In the representative embodiment, the high frequency voltage is applied between active and return electrode(s) 704 706 as the probe is withdrawn through the annulus 710. This voltage is sufficient to cause contraction of the collagen fibers within the annulus 710, which allows the annulus 710 to contract around the hole formed by probe 700, thereby improving the healing of this hole. Thus, the probe 700 seals its own passage as it is withdrawn from the disc.

Figs. 26-28 illustrate an alternative electrosurgical system 300 specifically configured for endoscopic discectomy procedures, e.g., for treating extruded or non-extruded herniated discs. As shown in Fig. 26 system 300 includes a trocar cannula 302 for introducing a catheter assembly 304 through a percutaneous penetration in the patient to a target disc in the patient's spine. As discussed above, the catheter assembly 304 may be introduced through the thorax in a thoracoscopic procedure, through the abdomen in a laparoscopic procedure, or directly through the patient's back. Catheter assembly 304 includes a catheter body 306 with a plurality of inner lumens (not shown) and a proximal

hub 308 for receiving the various instruments that will pass through catheter body 306 to the target site. In this embodiment, assembly 304 includes an electrosurgical instrument 310 with a flexible shaft 312, an aspiration catheter 314, an endoscope 316 and an illumination fiber shaft 318 for viewing the target site. As shown in Figs. 26 and 27, 5 aspiration catheter 314 includes a distal port 320 and a proximal fitment 322 for attaching catheter 314 to a source of vacuum (not shown). Endoscope 316 will usually comprise a thin metal tube 317 with a lens 324 at the distal end, and an eyepiece (not shown) at the proximal end.

In the exemplary embodiment, electrosurgical instrument 310 includes a 10 twist locking stop 330 at a proximal end of the shaft 312 for controlling the axial travel distance T_D of the probe. As discussed in detail below, this configuration allows the surgeon to "set" the distance of ablation within the disc. In addition, instrument 310 includes a rotational indicator 334 for displaying the rotational position of the distal portion of instrument 310 to the surgeon. This rotational indicator 334 allows the surgeon 15 to view this rotational position without relying on the endoscope 316 if visualization is difficult, or if an endoscope is not being used in the procedure.

Referring now to Fig. 27, a distal portion 340 of electrosurgical instrument 310 and catheter body 306 will now be described. As shown, instrument 310 comprises a relatively stiff, but deflectable electrically insulating support cannula 312 and a working 20 end portion 348 movably coupled to cannula 312 for rotational and translational movement of working end 348. Working end 348 of electrosurgical instrument 310 can be rotated and translated to ablate and remove a volume of nucleus pulposus within a disc. Support cannula 312 extends through an internal lumen 344 and beyond the distal end 346 of catheter body 306. Alternatively, support cannula 312 may be separate from instrument 25 310, or even an integral part of catheter body 306. The distal portion of working end 348 includes an exposed return electrode 350 separated from an active electrode array 352 by an insulating support member 354, such as ceramic. In the representative embodiment, electrode array 352 is disposed on only one side of ceramic support member 354 so that its other side is insulating and thus atraumatic to tissue. Instrument 310 will also include a 30 fluid lumen (not shown) having a distal port 360 in working end 348 for delivering electrically conductive fluid to the target site.

In use, trocar cannula 302 is introduced into a percutaneous penetration suitable for endoscopic delivery to the target disc in the spine. A trephine (not shown) or

other conventional instrument may be used to form a channel from the trocar cannula 302 through the annulus fibrosis 370 and into the nucleus pulposus. Alternatively, the probe 310 may be used for this purpose, as discussed above. The working end 348 of instrument 310 is then advanced through cannula 302 a short distance (e.g., about 7 to 10 mm) into 5 the nucleus pulposus 372, as shown in Fig. 28. Once the electrode array 352 is in position, electrically conductive fluid is delivered through distal port 360 to immerse the active electrode array 352 in the fluid. The vacuum source may also be activated to ensure a flow of conductive fluid between electrode array 352 past return electrode 350 to suction port 320, if necessary. In some embodiments, the mechanical stop 330 may then be set at 10 the proximal end of the instrument 310 to limit the axial travel distance of working end 348. Preferably, this distance will be set to minimize (or completely eliminate) ablation of 15 the surrounding annulus.

The probe is then energized by applying high frequency voltage difference between the electrode array 352 and return electrode 350 so that electric current flows 15 through the conductive fluid from the array 352 to the return electrode 350. The electric current causes vaporization of the fluid and ensuing molecular dissociation of the pulposus tissue as described in detail above. The instrument 310 may then be translated in an axial direction forwards and backwards to the preset limits. While still energized and translating, the working end 348 may also be rotated to ablate tissue surrounding the 20 electrode array 352. In the representative embodiment, working end 348 will also include an inflatable gland 380 opposite electrode array 352 to allow deflection of working end relative to support cannula 312. As shown in Fig. 28, working end 348 may be deflected 25 to produce a large diameter bore within the pulposus, which assures close contact with tissue surfaces to be ablated. Alternatively, the entire catheter body 306, or the distal end of catheter body 306 may be deflected to increase the volume of pulposus removed.

After the desired volume of nucleus pulposus is removed (based on direct observation through port 324, or by kinesthetic feedback from movement of working end 348 of instrument 310), instrument 310 is withdrawn into catheter body 306 and the catheter body is removed from the patient. Typically, the preferred volume of removed 30 tissue is about 0.2 cm³ to 5.0 cm³.

Referring now to Figs. 29-35, alternative systems and methods for ablating tissue in confined (e.g., narrow) body spaces will now be described. Fig. 29 illustrates an exemplary planar ablation probe 400 according to the present invention. Similar to the

instruments described above, probe 400 can be incorporated into electrosurgical system 11 (or other suitable systems) for operation in either the bipolar or monopolar modalities. Probe 400 generally includes a support member 402, a distal working end 404 attached to the distal end of support member 402 and a proximal handle 408 attached to the proximal 5 end of support member 402. As shown in Fig. 29, handle 406 includes a handpiece 408 and a power source connector 410 removably coupled to handpiece 408 for electrically connecting working end 404 with power supply 28 through cable 34 (see Fig. 1).

In the embodiment shown in Fig. 29, planar ablation probe 400 is configured to operate in the bipolar modality. Accordingly, support member 402 functions 10 as the return electrode and comprises an electrically conducting material, such as titanium, or alloys containing one or more of nickel, chromium, iron, cobalt, copper, aluminum, platinum, molybdenum, tungsten, tantalum or carbon. In the preferred embodiment, support member 402 is an austenitic stainless steel alloy, such as stainless steel Type 304 from MicroGroup, Inc., Medway, Massachusetts. As shown in Fig. 29, support member 15 402 is substantially covered by an insulating layer 412 to prevent electric current from damaging surrounding tissue. An exposed portion 414 of support member 402 functions as the return electrode for probe 400. Exposed portion 414 is preferably spaced proximally from active electrodes 416 by a distance of about 1 mm to 20 mm.

Referring to Figs. 30 and 31, planar ablation probe 400 further comprises a 20 plurality of active electrodes 416 extending from an electrically insulating spacer 418 at the distal end of support member 402. Of course, it will be recognized that probe 400 may include a single electrode depending on the size of the target tissue to be treated and the accessibility of the treatment site (see Fig. 35, for example). Insulating spacer 418 is preferably bonded to support member 402 with a suitable epoxy adhesive 419 to form a 25 mechanical bond and a fluid-tight seal. Electrodes 416 usually extend about 2.0 mm to 20 mm from spacer 418, and preferably less than 10 mm. A support tongue 420 extends from the distal end of support member 402 to support active electrodes 416. Support tongue 420 and active electrodes 416 have a substantially low profile to facilitate accessing narrow spaces within the patient's body, such as the spaces between adjacent vertebrae and 30 between articular cartilage and the meniscus in the patient's knee. Accordingly, tongue 420 and electrodes 416 have a substantially planar profile, usually having a combined height H_e of less than 4.0 mm, preferably less than 2.0 mm and more preferably less than

1.0 mm. The width of electrodes 416 and support tongue 420 will usually be less than 10.0 mm and preferably between about 2.0 mm to 4.0 mm.

Support tongue 420 includes a "non-active" surface 422 opposing active electrodes 416 covered with an electrically insulating layer (not shown) to minimize undesirable current flow into adjacent tissue or fluids. Non-active surface 422 is preferablyatraumatic, i.e., having a smooth planar surface with rounded corners, to minimize unwanted injury to tissue or nerves in contact therewith, such as disc tissue or the nearby spinal nerves, as the working end of probe 400 is introduced into a narrow, confined body space. Non-active surface 422 of tongue 420 help to minimize iatrogenic injuries to tissue and nerves so that working end 404 of probe 400 can safely access confined spaces within the patient's body.

Referring to Figs. 31 and 32, an electrically insulating support member 430 is disposed between support tongue 420 and active electrodes 416 to inhibit or prevent electric current from flowing into tongue 420. Insulating member 430 and insulating layer 412 preferably comprise a ceramic, glass or glass ceramic material, such as alumina. Insulating member 430 is mechanically bonded to support tongue 420 with a suitable epoxy adhesive to electrically insulate active electrodes 416 from tongue 420. Insulating member 430 may overhang support tongue 420 to increase the electrical path length between the active electrodes 416 and the insulation covered support tongue 420.

As shown in Figs. 31-33, active electrodes 416 are preferably constructed from a hollow, round tube, with at least the distal portion 432 of electrodes 416 being filed off to form a semi-cylindrical tube with first and second ends 440, 442 facing away from support tongue 420. Preferably, the proximal portion 434 of electrodes 416 will remain cylindrical to facilitate the formation of a crimp-type electrical connection between active electrodes 416 and lead wires 450 (see Fig. 33). Cylindrical proximal portions 434 of electrodes 416 extend beyond spacer 418 by a slight distance of 0.1 mm to 0.4 mm. The semi-cylindrical configuration of distal electrode portion 432 increases the electric field intensity and associated current density around the edges of ends 440, 442, as discussed above. Alternatively, active electrodes 416 may have any of the shapes and configurations described above or other configurations, such as square wires, triangular shaped wires, U-shaped or channel shaped wires and the like. In addition, the surface of active electrodes 416 may be roughened, e.g., by grit blasting, chemical or electrochemical etching, to

further increase the electric field intensity and associated current density around distal portions 432 of electrodes 416.

As shown in Fig. 34, each lead wire 450 terminates at a connector pin 452 contained in a pin insulator block 454 within handpiece 408. Lead wires 450 are covered with an insulation layer (not shown), e.g., Tefzel™, and sealed from the inner portion of support member 402 with an adhesive seal 457 (Fig. 32). In the preferred embodiment, 5 each electrode 416 is coupled to a separate source of voltage within power supply 28. To that end, connector pins 452 are removably coupled to mating receptacles 456 within connector 410 to provide electrical communication with active electrodes 416 and power supply 28 (Fig. 1). Electrically insulated lead wires 458 connect receptacles 456 to the corresponding sources of voltage within power supply 28. The electrically conductive wall 414 of support member 402 serves as the return electrode, and is suitably coupled to one of the lead wires 450.

In an alternative embodiment, adjacent electrodes 416 may be connected to 15 the opposite polarity of source 28 so that current flows between adjacent active electrodes 416 rather than between active electrodes 416 and return electrode 414. By way of example, Fig. 31B illustrates a distal portion of a planar ablation probe 400' in which electrodes 416a and 416c are at one voltage polarity (i.e., positive) and electrodes 416b and 416d are at the opposite voltage polarity (negative). When a high frequency voltage is 20 applied between electrodes 416a, 416c and electrodes 416b, 416d in the presence of electrically conducting liquid, current flows between electrodes 416a, 416c and 416b, 416d as illustrated by current flux lines 522'. Similar to the above embodiments, the opposite surface 420 of working end 404' of probe 400' is generallyatraumatic and electrically 25 insulated from active electrodes 416a, 416b, 416c and 416d to minimize unwanted injury to tissue in contact therewith.

In an exemplary configuration, each source of voltage includes a current limiting element or circuitry (not shown) to provide independent current limiting based on the impedance between each individual electrode 416 and return electrode 414. The current limiting elements may be contained within the power supply 28, the lead wires 30 450, cable 34, handle 406, or within portions of the support member 402 distal to handle 406. By way of example, the current limiting elements may include resistors, capacitors, inductors, or a combination thereof. Alternatively, the current limiting function may be performed by (1) a current sensing circuit which causes the interruption of current flow if

the current flow to the electrode exceeds a predetermined value and/or (2) an impedance sensing circuit which causes the interruption of current flow (or reduces the applied voltage to zero) if the measured impedance is below a predetermined value. In another embodiment, two or more of the electrodes 416 may be connected to a single lead wire 450 such that all of the electrodes 416 are always at the same applied voltage relative to return electrode 414. Accordingly, any current limiting elements or circuits will modulate the current supplied or the voltage applied to the array of electrodes 416, rather than limiting their current individually, as discussed in the previous embodiment.

Referring to Fig. 35, a method for ablating tissue structures with planar ablation probe 400 according to the present invention will now be described. . In particular, exemplary methods for removing soft tissue 540 from the surfaces of adjacent vertebrae 542, 544 in the spine will be described. In this procedure, at least the working end 404 of planar ablation probe 400 is introduced to a treatment site either by minimally invasive techniques or open surgery. Electrically conducting liquid is delivered to the treatment site, and voltage is applied from power supply 28 between active electrodes 416 and return electrode 414. The voltage is preferably sufficient to generate electric field intensities near active electrodes that form a vapor layer in the electrically conducting liquid, and induce the discharge of energy from the vapor layer to ablate tissue at the treatment site, as described in detail above.

Removal of this soft tissue 540 is often necessary, for example, in surgical procedures for fusing or joining adjacent vertebrae together. Following the removal of tissue 540, the adjacent vertebrae 542, 544 are stabilized to allow for subsequent fusion together to form a single monolithic vertebra. As shown, the low-profile of working end 404 of probe 400 (i.e., thickness values as low as 0.2 mm) allows access to and surface preparation of closely spaced vertebrae. In addition, the shaped electrodes 416 promote substantially high electric field intensities and associated current densities between active electrodes 416 and return electrode 414 to allow for the efficient removal of tissue attached to the surface of bone without significantly damaging the underlying bone. The "non-active" insulating side 521 of working end 404 also minimizes the generation of electric fields on this side 521 to reduce ablation of the adjacent vertebra 542.

The target tissue is generally not completely immersed in electrically conductive liquid during surgical procedures within the spine, such as the removal of soft tissue described above. Accordingly, electrically conducting liquid will preferably be

delivered into the confined spaces 513 between adjacent vertebrae 542, 544 during this procedure. The fluid may be delivered through a liquid passage (not shown) within support member 402 of probe 400, or through another suitable liquid supply instrument.

Referring now to Figs. 36-38 an alternative electrode support member 500 for a planar ablation probe 404 will be described in detail. As shown, electrode support member 500 preferably comprises a multilayer or single layer substrate 502 comprising a suitable high temperature, electrically insulating material, such as ceramic. The substrate 502 is a thin or thick film hybrid having conductive strips that are adhered to, e.g., plated onto, the ceramic wafer. The conductive strips typically comprise tungsten, gold, nickel or equivalent materials. In the exemplary embodiment, the conductive strips comprise tungsten, and they are co-fired together with the wafer layers to form an integral package. The conductive strips are coupled to external wire connectors by holes or vias that are drilled through the ceramic layers, and plated or otherwise covered with conductive material.

In the representative embodiment, support member 500 comprises a single ceramic wafer having a plurality of longitudinal ridges 504 formed on one side of the wafer 502. Typically, the wafer 502 is green pressed and fired to form the required topography (e.g., ridges 504). A conductive material is then adhered to the ridges 502 to form conductive strips 506 extending axially over wafer 502 and spaced from each other. As shown in Fig. , the conductive strips 506 are attached to lead wires 508 within shaft 412 of the probe 404 to electrically couple conductive strips 506 with the power supply 28 (Fig. 1). This embodiment provides a relatively low profile working end of probe 404 that has sufficient mechanical structure to withstand bending forces during the procedure.

Figs. 39A to 41 illustrate systems and methods for treating and ablating spinal discs according to the present invention. Electrosurgical probe 800 generally comprises a shaft 802 that can be percutaneously introduced anteriorly through the abdomen or thorax, or posteriorly through the patient's back directly into the spine. The probe shaft 802 will include one or more active electrode(s) 804 for applying electrical energy to the spinal disc. The system may include one or more return electrode(s) 806. The return electrode(s) 806 can be positioned proximal of the active electrode(s) 804 on the electrosurgical probe or on a separate instrument (not shown). The ablation probe 800 shown in Fig. 39A is configured to operate in the bipolar modality. In alternative

embodiments, however, the return electrode 806 may be positioned on the patient's back, as a dispersive pad (not shown) so as to operate in a monopolar modality.

In the exemplary embodiment shown in Figs. 39A and 39B, the distal end of the shaft 802 is curved or bent to improve access to the disk being treated. The treatment surface 808 of the electrosurgical probe is usually curved or bent to an angle of about 10 degrees to 90 degrees relative to the longitudinal axis of shaft 100, preferably about 15 degrees to 60 degrees and more preferably about 15 degrees. In alternative embodiments, the distal portion of shaft 802 comprises a flexible material which can be deflected relative to the longitudinal axis of the shaft. Such deflection may be selectively induced by mechanical tension of a pull wire, for example, or by a shape memory wire that expands or contracts by externally applied temperature changes. A more complete description of this embodiment can be found in U.S. Patent No. 5,697,909, the complete disclosure of which has previously been incorporated herein by reference. Alternatively, the shaft 802 of the present invention may be bent by the physician to the appropriate angle using a conventional bending tool or the like.

The active electrode(s) 804 typically extend from an active tissue treatment surface of an electrode support member 810 of the probe shaft 802. Opposite of the active electrodes 802 is a non-active insulating side 812, which has an insulator 814 that is configured to protect the dura mater 816 and other non-target spinal cord tissue 818. The insulator 814 minimizes the generation of electric fields on the non-active side and reduces the electrical damage to the dura mater 816 and spinal column 818 during disc ablation. While the insulator 814 is shown opposite of the active electrode array 804, it will be appreciated that the insulator 814 can be positioned completely around the probe, be positioned around only portions of the probe, be along the sides of the active electrode array, and the like.

The tissue treatment surface 808 and individual active electrodes 804 will usually have dimensions within the ranges set forth above. In some embodiments, the active electrodes 804 can be disposed within or on an insulating support member 810, as described above. In the representative embodiment, the surface of the active electrodes 804 has a circular cross-sectional shape with a diameter in the range of about 1 mm to 30 mm, usually about 2 mm to 20 mm. The individual active electrodes 802 preferably extend outward from tissue treatment surface 808 by a distance of about 0.1 mm to 8 mm, usually about 0.2 mm to 4 mm. Applicant has found that this configuration increases the

high electric field intensities and associated current densities around active electrodes 104 to facilitate the ablation of tissue as described in detail above. Of course, it will be recognized that the active electrodes may have a variety of different configurations. For example, instead of an array of active electrodes, a single active electrode may be used.

5 An exemplary method for ablating and removing the target spinal disc 822 will now be described. Removal of the degenerative or damaged disc 822 is necessary, for example, in surgical procedures during placement of a cage or the fusing or joining adjacent vertebrae together. Following the removal of the disc 822, the adjacent vertebrae 824 are stabilized to allow for subsequent fusion together to form a single monolithic 10 vertebra. During such procedures it would be preferable to protect the dura mater 816 and spinal cord 818 from damage from the electrosurgical probe 800.

In use, the distal end of probe 800 is introduced into a treatment site either by minimally invasive techniques or open surgery. The distal portion of electrosurgical probe 800 can be introduced through a percutaneous penetration 826, such as a cannula, 15 into the body cavity 828. The insertion of probe 800 is usually guided by an endoscope (not shown) which can include a light source and a video camera to allow the surgeon to selectively visualize a zone within the vertebral column. The distal portion of shaft 802 can be introduced anteriorly through a small percutaneous penetration into the annulus 820 of the target spinal disc 822 (Figs. 40) or the distal portion of the shaft 802 can be 20 introduced posteriorly through a small percutaneous penetration in the back (Fig. 41).

To maintain a clear field of view and to facilitate the generation of a vapor layer, a transparent, electrically conductive irrigant (not shown), such as isotonic saline, can be injected into the treatment site either through a liquid passage in probe 800, or through another instrument. Suitable methods for delivering irrigant to a treatment site are 25 described in commonly assigned, co-pending application U.S. Patent No. 5,697,281 filed on June 7, 1995 (Attorney Docket 16238-000600), previously incorporated herein by reference.

After (or during) introduction of the electrosurgical probe 800 into the spinal disc 822, an electrically conductive liquid 830 can be delivered to the treatment site, 30 and voltage can be applied from power supply 28 between active electrodes 804 and return electrode 806 through the conductive fluid. The voltage is preferably sufficient to generate electric field intensities near active electrodes 806 that form a vapor layer in the electrically conductive liquid so as to induce a discharge of energy from the vapor layer to

ablate tissue at the treatment site, as described in detail above. As the probe shaft 802 is moved through the spinal disc 822, the insulator 812 can be positioned to engage the dura mater 816 and protect the dura mater 816 (and spinal cord 818) from damaging electrical current flow.

5 Figs. 42 to 43 show yet another embodiment of the present invention. The electrosurgical probe 800 includes an aspiration lumen 832 for aspirating the target area and a fluid delivery lumen 834 for directing an electrically conductive fluid 830 to the target area. In some implementations, the aspiration lumen 832 and the fluid delivery lumen 834 are coupled together in an annular pattern along the exterior of the electrosurgical probe. A distal end of the aspiration lumen 832 typically ends proximal of the return electrode 806 while the distal end of the fluid delivery lumen 834 extends to a point adjacent the distal end of the electrosurgical probe 800. As shown in Fig. 43, the fluid delivery lumen 834 preferably occupies a larger portion of the annular region. In one specific embodiment, the fluid delivery lumen occupies approximately two-thirds of the 10 annular region.

15

The electrosurgical probe may have a single active electrode 804 or an electrode array distributed over a contact surface of a probe. In the latter embodiment, the electrode array usually includes a plurality of independently current-limited and/or power-controlled active electrodes to apply electrical energy selectively to the target tissue while 20 limiting the unwanted application of electrical energy to the surrounding tissue and environment. In one specific configuration the electrosurgical probe comprises 23 active electrodes. Of course, it will be appreciated that that the number, size, and configuration of the active electrodes may vary depending on the specific use of the electrosurgical probe (e.g. tissue contraction, tissue ablation, or the like).

25 The shaft 802 will usually house a plurality of wires or other conductive elements axially therethrough to permit connection of the electrode array 804 to a connector at the proximal end of the shaft (not shown). The active electrode array may be connected to a separate power source that is isolated from the other active electrodes. Alternatively, the active electrodes may be connected to each other at either the proximal 30 or distal ends of the probe to form a single wire that couples to a power source.

The active electrode(s) 804 are typically supported by an electrically insulating electrode support member 836 that extends from the electrosurgical probe 800. Electrode support member 836 typically extends from the distal end of shaft 802 about

1 mm to 20 mm. Electrode support member 836 typically comprises an insulating material (e.g., ceramic or glass material, such as alumina, zirconia and the like) which could be formed at the time of manufacture in a flat, hemispherical or other shape according to the requirements of a particular procedure.

5 In use, the electrosurgical probe 800 can be positioned adjacent the target tissue, as described above. When treating discs, the distal end of shaft is typically delivered through the annulus to the nucleus pulposus 821, which may be herniated, extruded, non-extruded, or simply swollen. As shown in Fig. 44, high frequency voltage is applied between active electrode(s) 804 and return electrode(s) 806 to heat the
10 surrounding collagen to suitable temperatures for contraction (i.e., typically about 55°C to about 70°C) or ablation (i.e. typically less than 150°C). As discussed above, this procedure may be accomplished with a monopolar configuration, as well. However, applicant has found that the bipolar configuration provides enhanced control of the high frequency current, which reduces the risk of spinal nerve damage.

15 In the exemplary embodiments, an electrically conductive fluid 830 is delivered through fluid delivery lumen 834 to the target site. In these embodiments, the high frequency voltage applied to the active electrode(s) is sufficient to vaporize the electrically conductive fluid (e.g., gel or saline) between the active electrode(s) and the tissue. Within the vaporized fluid, a ionized plasma is formed and charged particles (e.g.,
20 electrons) are accelerated towards the tissue to cause the molecular breakdown or disintegration of several cell layers of the tissue. This molecular dissociation is accompanied by the volumetric removal of the tissue. Because the aspiration lumen 832 is placed proximal of the return electrode (and typically outside of the spinal disc 822), the aspiration lumen 832 typically removes the air bubbles from the spinal disc and leaves the
25 disc tissue relatively intact. Moreover, because the aspiration lumen 834 is spaced from the target area, the conductive fluid 830 is allowed to stay in the target area longer and the plasma can be created more aggressively.

Figs. 45A to 45D show embodiments of the electrosurgical probe of the present invention which have a curved or steerable distal tip for improving navigation of
30 the electrosurgical probe 800 within the disc. Referring now to Fig. 45A, probe 800 comprises an electrically conductive shaft 802, a handle 803 coupled to the proximal end of shaft 802 and an electrically insulating support member 836 at the distal end of shaft 802. Probe 800 further includes an insulating sleeve 838 over shaft 802, and an exposed

portion of shaft 802 that functions as the return electrode 806. In the representative embodiment, probe 800 comprises a plurality of active electrodes 804 extending from the distal end of support member 836. As shown, return electrode 806 is spaced a further distance from active electrodes 804 than in the embodiments described above. In this 5 embodiment, the return electrode 806 is spaced a distance of about 2.0 mm to 50 mm, preferably about 5 mm to 25 mm. In addition, return electrode 806 has a larger exposed surface area than in previous embodiments, having a length in the range of about 2.0 mm to 40 mm, preferably about 5 mm to 20 mm. Accordingly, electric current passing from active electrodes 804 to return electrode 806 will follow a current flow path 840 that is 10 further away from shaft 802 than in the previous embodiments. In some applications, this current flow path 840 results in a deeper current penetration into the surrounding tissue with the same voltage level, and thus increased thermal heating of the tissue. As discussed above, this increased thermal heating may have advantages in some applications of treating disc or other spinal abnormalities. Typically, it is desired to achieve a tissue temperature 15 in the range of about 60°C to 100°C to a depth of about 0.2 mm to 5 mm, usually about 1 mm to 2 mm. The voltage required for this thermal damage will partly depend on the electrode configurations, the conductivity of the tissue and the area immediately surrounding the electrodes, the time period in which the voltage is applied and the depth of tissue damage desired. With the electrode configurations described in Figs. 45A-45D, the 20 voltage level for thermal heating will usually be in the range of about 20 volts rms to 300 volts rms, preferably about 60 volts rms to 200 volts rms. The peak-to-peak voltages for thermal heating with a square wave form having a crest factor of about 2 are typically in the range of about 40 to 600 volts peak-to-peak, preferably about 120 to 400 volts peak-to-peak. The higher the voltage is within this range, the less time required. If the voltage is 25 too high, however, the surface tissue may be vaporized, debulked or ablated, which is often undesirable.

As shown by the dotted lines in Figs. 45A-45D, the distal tip 837 of the electrosurgical probe 800 can have a pre-formed curvature or can be steered to a curved configuration so as to approximate the curvature of the inner surface 839 of the annulus 30 (Fig. 46). In some embodiments the distal tip 837 is made of a shape memory material that can be shaped to approximate the inside curvature of the annulus. In other embodiments, the distal tip 837 of the electrosurgical probe 800 is steerable or deflectable by the user. The flexible shaft and steerable distal tip may be combined with pull wires,

shape memory actuators, heat actuated materials, or other conventional or proprietary mechanisms for effecting selective deflection of the distal tip of the shaft to facilitate positioning of the electrode array. A user can track the position of the steerable distal tip using fluoroscopy, optical fibers, transducers positioned on the probe, or the like.

5 In some embodiments, the electrosurgical probe 800 may include a dispersive return electrode 842 (Fig. 46) for switching between bipolar and monopolar modes. In this embodiment, the power supply 28 will typically include a switch, e.g., a foot pedal 843, for switching between the monopolar and bipolar modes. The system will switch between an ablation mode, where the dispersive pad 842 is deactivated and voltage
10 is applied between active and return electrodes 804, 806, and a subablation or thermal heating mode, where the active electrode(s) 804 and deactivated and voltage is applied between the dispersive pad 842 and the return electrode 806. In the subablation mode, a lower voltage is typically applied and the return electrode 806 functions as the active electrode to provide thermal heating and/or coagulation of tissue surrounding return
15 electrode 806. A more complete description of the use of the dispersive return electrode is described in co-pending U.S. Patent Application Serial No. 09/316,472, filed May 21, 1999, the complete disclosure of which was previously incorporated by reference.

Fig. 45B illustrates yet another embodiment of the present invention. As shown, electrosurgical probe 800 comprises an electrode assembly having one or more active electrode(s) 804 and a proximally spaced return electrode 806 as in previous
20 embodiments. Return electrode 806 is typically spaced about 0.5 mm to 25 mm, preferably 1.0 mm to 5.0 mm from the active electrode(s) 804, and has an exposed length of about 1 mm to 20 mm. In addition, the electrode assembly can include two additional electrodes 844, 846 spaced axially on either side of return electrode 806. Electrodes 844,
25 846 are typically spaced about 0.5 mm to 25 mm, preferably about 1 mm to 5 mm from return electrode 806. In the representative embodiment, the additional electrodes 844, 846 are exposed portions of shaft 802, and the return electrode 806 is electrically insulated from shaft 802 such that a voltage difference may be applied between electrodes 844, 846 and electrode 804. In this embodiment, probe 800 may be used in at least two different
30 modes, an ablation mode and a subablation or thermal heating mode. In the ablation mode, voltage is applied between active electrode(s) 804 and return electrode 806 in the presence of electrically conductive fluid, as described above. In the ablation mode, electrodes 844, 846 are deactivated. In the thermal heating or coagulation mode, active

electrode(s) 804 are deactivated and a voltage difference is applied between electrodes 844, 846 and electrode 806 such that a high frequency current 840 flows therebetween, as shown in Fig. 15B. In the thermal heating mode, a lower voltage is typically applied below the threshold for plasma formation and ablation, but sufficient to cause some 5 thermal damage to the tissue immediately surrounding the electrodes without vaporizing or otherwise debulking this tissue so that the current 840 provides thermal heating and/or coagulation of tissue surrounding electrodes 804, 844, 846.

Fig. 45C illustrates another embodiment of probe 800 incorporating an electrode assembly having one or more active electrode(s) 804 and a proximally spaced return electrode 806 as in previous embodiments. Return electrode 806 is typically spaced about 0.5 mm to 25 mm, preferably 1.0 mm to 5.0 mm from the active electrode(s) 804, and has an exposed length of about 1 mm to 20 mm. In addition, the electrode assembly includes a second active electrode 848 separated from return electrode 360 by an electrically insulating spacer 382. In this embodiment, handle 803 includes a switch 850 for toggling probe 800 between at least two different modes, an ablation mode and a subablation or thermal heating mode. In the ablation mode, voltage is applied between active electrode(s) 804 and return electrode 806 in the presence of electrically conductive fluid, as described above. In the ablation mode, electrode 848 is deactivated. In the thermal heating or coagulation mode, active electrode(s) 806 may be deactivated and a 10 voltage difference is applied between electrode 848 and electrode 806 such that a high frequency current 840 flows therebetween. Alternatively, active electrode(s) 804 may not be deactivated as the higher resistance of the smaller electrodes may automatically send the electric current to electrode 848 without having to physically decouple electrode(s) 804 from the circuit. In the thermal heating mode, a lower voltage is typically applied below 15 the threshold for plasma formation and ablation, but sufficient to cause some thermal damage to the tissue immediately surrounding the electrodes without vaporizing or otherwise debulking this tissue so that the current 840 provides thermal heating and/or coagulation of tissue surrounding electrodes 804, 848.

Fig. 45D illustrates yet another embodiment of the invention designed for 20 channeling through tissue and creating lesions therein to treat the interior tissue of spinal discs. As shown, probe 800 is similar to the probe in Fig. 45C having a return electrode 806 and a third, coagulation electrode 848 spaced proximally from the return electrode 806. In this embodiment, active electrode 804 comprises a single electrode wire extending

distally from insulating support member 836. Of course, the active electrode 804 may have a variety of configurations to increase the current densities on its surfaces, e.g., a conical shape tapering to a distal point, a hollow cylinder, loop electrode and the like. In the representative embodiment, support members 836 and 852 are constructed of inorganic material, such as ceramic, glass, silicone and the like. The proximal support member 852 may also comprise a more conventional organic material as this support member 852 will generally not be in the presence of a plasma that would otherwise etch or wear away an organic material.

The probe 800 in Fig. 45D does not include a switching element. In this embodiment, all three electrodes are activated when the power supply is activated. The return electrode 806 has an opposite polarity from the active and coagulation electrodes 804, 848 such that current 840 flows from the latter electrodes to the return electrode 806 as shown. In the preferred embodiment, the electrosurgical system includes a voltage reduction element or a voltage reduction circuit for reducing the voltage applied between the coagulation electrode 848 and return electrode 806. The voltage reduction element allows the power supply 28 (Fig. 1) to, in effect, apply two different voltages simultaneously to two different electrodes. Thus, for channeling through tissue, the operator may apply a voltage sufficient to provide ablation of the tissue at the tip of the probe (i.e., tissue adjacent to the active electrode 804). At the same time, the voltage applied to the coagulation electrode 848 will be insufficient to ablate tissue. For thermal heating or coagulation of tissue, for example, the voltage reduction element will serve to reduce a voltage of about 100 volts rms to 300 volts rms to about 45 volts rms to 90 volts rms, which is a suitable voltage for coagulation of tissue without ablation (e.g., molecular dissociation) of the tissue.

In the representative embodiment, the voltage reduction element is a capacitor (not shown) coupled to the power supply and coagulation electrode 848. The capacitor usually has a capacitance of about 200 pF to 500 pF (at 500 volts) and preferably about 300 pF to 350 pF (at 500 volts). Of course, the capacitor may be located in other places within the system, such as in, or distributed along the length of, the cable, the generator, the connector, etc. In addition, it will be recognized that other voltage reduction elements, such as diodes, transistors, inductors, resistors, capacitors or combinations thereof, may be used in conjunction with the present invention. For example, the probe 800 may include a coded resistor (not shown) that is constructed to

lower the voltage applied between the return and coagulation electrodes 806, 848. In addition, electrical circuits may be employed for this purpose.

Of course, for some procedures, the probe will typically not require a voltage reduction element. Alternatively, the probe may include a voltage increasing element or circuit, if desired. Alternatively or additionally, the cable 22 that couples the power supply 28 to the probe may be used as a voltage reduction element (Fig. 1). The cable has an inherent capacitance that can be used to reduce the power supply voltage if the cable is placed into the electrical circuit between the power supply, the active electrodes and the return electrode. In this embodiment, the cable 22 may be used alone, or in combination with one of the voltage reduction elements discussed above, e.g., a capacitor. Further, it should be noted that the present invention can be used with a power supply that is adapted to apply two different voltages within the selected range for treatment of tissue. In this embodiment, a voltage reduction element or circuitry may not be desired.

In use, the electrosurgical instruments of Figs. 45A-45D can be used to treat the tissue within the disc 822. In particular, the electrosurgical instrument 800 can be used to treat damaged discs (e.g., herniated, bulging, fissured, protruding, or the like), denervate selective nerves embedded in the annulus, cauterize granulation tissue that is ingrown into the annulus, seal fissures along the inner surface of the annulus, and the like.

Preferably, the electrosurgical probe 800 can achieve these results in a minimally destructive manner so as to maintain the water content and tissue mass within the disc. Of course, the present invention can also be adapted to ablate tissue or reduce the water content within the disc.

In preferred embodiments, the electrosurgical probe 800 minimizes ablation of the nucleus pulposus 821 by moving along an inner surface of the annulus 822.

Accordingly, after the distal tip of the electrosurgical probe is inserted into the disc 820 (Fig. 45), the distal tip 837 can be steered along the interface between the annulus and nucleus pulposus 821.

Referring now to Fig. 47, in most methods the physician positions active electrode 804 adjacent to the tissue surface to be treated (i.e., a spinal disc). The power supply is activated to provide an ablation voltage between active and return electrodes 804, 806 and a coagulation or thermal heating voltage between coagulation and return electrodes 806, 848. An electrically conductive fluid can then be provided around active electrode 804, and in the junction between the active and return electrodes 804, 806 to provide a

current flow path therebetween. This may be accomplished in a variety of manners, as discussed above. The active electrode 804 is then advanced through the space left by the ablated tissue to form a channel in the disc. During ablation, the electric current between the coagulation and return electrode is typically insufficient to cause any damage to the 5 surface of the tissue as these electrodes pass through the tissue surface into the channel created by active electrode 804. Once the physician has formed the channel to the appropriate depth, he or she will cease advancement of the active electrode, and will either hold the instrument in place for approximately 5 seconds to 30 seconds, or can immediately remove the distal tip of the instrument from the channel (see detailed 10 discussion of this below). In either event, when the active electrode is no longer advancing, it will eventually stop ablating tissue.

Prior to entering the channel formed by the active electrode 804, an open circuit exists between return and coagulation electrodes 806, 848. Once coagulation electrode 848 enters this channel, electric current will flow from coagulation electrode 15 848, through the tissue surrounding the channel, to return electrode 806. This electric current will heat the tissue immediately surrounding the channel to coagulate any severed vessels at the surface of the channel. If the physician desires, the instrument may be held within the channel for a period of time to create a lesion around the channel.

In an exemplary embodiment, once the distal tip 837 of the electrosurgical 20 probe 800 has channeled through the annulus fibrosus 822, the distal tip 837 can be steered or deflected so as to move along the inner surface of the annulus fibrosus 822. As shown in Figs. 48A and 48B, the electrosurgical device is advanced into the disc and the physician can simultaneously steer the distal tip from the proximal end of the 25 electrosurgical device (not shown). As noted above, the distal end of the electrosurgical device preferably is steered or deflected around the inner surface of the annulus 822. The physician can use fluoroscopy to monitor the position and movement of the distal end of the probe. Alternatively, the surgeon may insert an imaging device or transducer directly into the disc to monitor the position of the electrode array. The imaging device (not shown) can be positioned on the electrosurgical probe or it can be on a separate 30 instrument.

In other embodiments, instead of a steerable distal tip 837, the distal tip of the electrosurgical probe 800 can be composed of a shape-memory material that can be pre-shaped to have the approximate curve of the inner surface of the annulus. The shape-

memory tip can be biased to a pre-bent curved configuration, such that in the absence of a straightening force (e.g., within the annulus, within a tube, or the like) the distal tip will bias to the curved configuration. For example, after an operating corridor has been created to the target site, the electrosurgical probe can be moved adjacent the outer surface 5 of the annulus. The active electrode can channel through the tough annulus fibrosus 822, as described above. Once the distal tip 837 enters the nucleus pulposus 821, the distal tip will no longer be constrained in the substantially straight configuration by the tough, annulus fibrosus 822 and the distal tip will bias to its pre-bent curved configuration. As the electrosurgical device is advanced into the disc 820, the biased distal tip encourages the 10 electrosurgical instrument to follow the curved inner surface 839 of the annulus fibrosus.

As described in detail above, once the electrosurgical probe has been steered to the target position, the high frequency voltage can be delivered between the active electrode(s) and return electrode(s) in a bipolar mode or monopolar mode to treat the inner surface 839 of the annulus fibrosus. In some embodiments, an electrically conductive 15 fluid, such as isotonic saline, can be delivered to the active electrode. As noted above, in procedures requiring ablation of tissue, the tissue is removed by molecular dissociation or disintegration processes. In these embodiments, the high frequency voltage applied to the active electrode(s) is sufficient to vaporize the electrically conductive fluid between the active electrode(s) and the tissue. Within the vaporized fluid, a ionized plasma is formed 20 and charged particles (e.g., electrons) are accelerated towards the tissue to cause the molecular breakdown or disintegration of several cell layers of the tissue. This molecular dissociation is accompanied by the volumetric removal of the tissue. The short range of the accelerated charged particles within the plasma layer confines the molecular 25 dissociation process to the surface layer to minimize damage and necrosis to the underlying spinal disc tissue. In monopolar embodiments, the conductive fluid need only be sufficient to surround the active electrode and to provide a layer of fluid between the electrode and the tissue. In bipolar embodiments, the conductive fluid preferably generates a current flow path between the active electrode(s) and the return electrode(s).

Depending on the procedure, the inner surface 839 of the annulus can be 30 ablated, contracted, sealed, or the like. For example, the high frequency voltage can be used to denervate the pain receptors in a fissure in the annulus fibrosis, deactivate the neurotransmitters, deactivate heat-sensitive enzymes, denervating nerves embedded in the

wall of the annulus fibrosis, ablate granulation tissue in the annulus fibrosus, shrink collagen in the annulus fibrosus, or the like.

WHAT IS CLAIMED IS:

1. A method for treating intervertebral discs:
positioning an active electrode adjacent to a disc;
applying high frequency voltage between the active electrode and a return
5 electrode, the high frequency voltage being sufficient to ablate the disc tissue;
during the applying step, advancing the active electrode into the disc tissue
to generate a space within the tissue; and
removing the active electrode from the space within the tissue.

10 2. The method of claim 1 further comprising, during the
removing step, applying high frequency voltage between the active and return electrodes,
the high frequency voltage being sufficient to coagulate blood at the tissue surface
surrounding the space.

15 3. The method of claim 1 further comprising providing an electrically
conductive fluid around the active electrode and between the active and return electrodes
prior to the applying step.

20 4. The method of claim 3 further comprising generating a current flow
path between the active and return electrodes with the electrically conductive fluid.

5. The method of claim 1 wherein the active electrode comprises a
single, active electrode at the distal end of a shaft.

25 6. The method of claim 1 wherein the active electrode comprises a
plurality of electrically isolated electrode terminals at the distal end of a shaft.

7. The method of claim 3 further comprising aspirating fluid from the
target site.

8. The method of claim 2 wherein the high frequency voltage during the removal step is sufficient to thermally damage the surface of the disc tissue surrounding the space.

5 9. The method of claim 1 further comprising axially translating the active electrode to form a hole through at least a portion of the disc tissue.

10 10. The method of claim 1 further comprising transversely translating the active electrode relative to the disc tissue to form a channel along a surface of the disc.

11. The method of claim 1 wherein the active and return electrodes are both located on a shaft of an electrosurgical instrument.

12. The method of claim 1 further comprising introducing at least the 15 distal end portion of the shaft through a percutaneous penetration in the patient to the disc.

13. The method of claim 1 wherein the return electrode is axially spaced at least about 1.0 mm from the active electrode.

20 14. The method of claim 1 further comprising, during the removal step, deactivating the active electrode and applying a high frequency voltage difference between a second active electrode and one or more return electrodes on the instrument shaft.

25 15. The method of claim 14 wherein the second active electrode is spaced proximally from the return electrode.

30 16. The method of claim 15 wherein the instrument shaft comprises a second return electrode spaced proximally from the second active electrode, the method comprising, during the removal step, applying a high frequency voltage difference between the second active electrode and the first and second return electrodes.

17. The method of claim 1 further comprising, during the removal step,

deactivating the active electrode and applying a high frequency voltage difference between the return electrode on the instrument shaft and a dispersive return electrode coupled to an external surface of the patient.

5 18. A method for treating intervertebral discs comprising:
positioning an active electrode adjacent to, or within, a patient's spinal disc;
and

10 applying high frequency voltage between the active electrode and a return electrode, the high frequency voltage being sufficient to modify a tissue structure within the spinal disc such that a volume of the spinal disc is reduced.

15 19. The method of claim 18 wherein the applying step comprises
applying sufficient voltage between the active and return electrodes to thermally damage the tissue structure.

20 20. The method of claim 18 further comprising, prior to the applying step, ablating a portion of the tissue structure to form a space within the tissue structure, and then applying sufficient high frequency voltage to modify the surface immediately surrounding the space.

25 21. The method of claim 18 further comprising reducing a sufficient volume of the spinal disc to decompress a nerve in or around the spinal disc.

22. A method for treating a degenerative intervertebral disc comprising:
positioning one or more active electrode(s) adjacent to selected nerves embedded in the walls of an intervertebral disc;
positioning one or more return electrode(s) in the vicinity of the active electrode(s) in or around the intervertebral disc; and
applying a sufficient high frequency voltage difference between the active and return electrodes to denervate the selected nerves.

30 23. A method for treating degenerative intervertebral discs comprising:

positioning one or more active electrode(s) adjacent to or within the nucleus pulposis of an intervertebral;

positioning one or more return electrode(s) in the vicinity of the active electrode(s) in or around the intervertebral disc; and

5 applying a sufficient high frequency voltage difference between the active and return electrodes to reduce water content of the nucleus pulposis and shrink the collagen fibers within the nucleus pulposis to tighten the disc.

24 A method for treating degenerative intervertebral discs comprising:

10 positioning one or more active electrode(s) adjacent to an annular fissure on the inner wall of the annulus fibrosis of an intervertebral disc;

positioning one or more return electrode(s) in the vicinity of the active electrode(s) in or around the intervertebral disc; and

15 applying a sufficient high frequency voltage difference between the active and return electrodes to shrink the collagen fibers in the annular fissure.

25. A system for treating intervertebral discs comprising:

an electrosurgical instrument having a shaft with a proximal end portion and a distal end portion;

20 an electrode assembly comprising at least one active electrode positioned on the distal portion of the shaft, and at least one return electrode positioned on the shaft and axially spaced from the active electrode;

a coagulation electrode; and

25 electrodes, the power supply being capable of applying a first high frequency voltage difference between the active and return electrodes sufficient to ablate tissue, and a second high frequency voltage difference between the return electrode and the third electrode sufficient to coagulate blood and insufficient to ablate tissue.

30 26. The system of claim 25 wherein the coagulation electrode is positioned on the shaft and axially spaced from the return electrode.

27. The system of claim 25 wherein the distal end portion of the shaft is sized for delivery through a percutaneous opening in the patient to a spinal disc.

28. The system of claim 25 further comprising a voltage reduction
5 element coupled between the power source and the coagulation electrode to reduce the voltage applied to the coagulation electrode.

29. The system of claim 25 wherein the coagulation electrode comprises
a dispersive return electrode configured for attachment to an external skin surface of the
10 patient.

30. The system of claim 25 wherein the power applies the first and
second high frequency voltage differences at the same time

15 31. The system of claim 25 wherein the coagulation electrode is located
on the instrument shaft and spaced axially from the active and return electrodes.

32. The system of claim 25 further comprising a switch for moving
between an ablation mode, wherein the third electrode is deactivated and the power supply
20 applies a high frequency voltage difference between the active and return electrodes
sufficient to ablate tissue, and a thermal mode, wherein the active electrode is deactivated
and the power supply applies a high frequency voltage difference between the return
electrode and the third electrode sufficient to coagulate blood and insufficient to ablate
tissue.

25 33. The system of claim 25 wherein the second high frequency voltage
difference is in the range of about 20 to 90 volts rms and the first high frequency voltage
difference is in the range of about 150 to 350 volts rms.

30 34. The system of claim 25 wherein the coagulation electrode comprises
an annular band spaced proximally from the return electrode and having a substantially
smooth, exposed surface to reduce current densities on said surface.

35. The system of claim 25 wherein the exposed surface of the coagulation electrode has a larger surface area than the exposed surface of the return electrode.

5 36. A method for treating a disc within a patient's spine, the spine comprising a dura mater surrounding a spinal cord, the method comprising:

positioning at least one active electrode within close proximity of a disc in the patient's spine;

insulating the dura mater from the active electrode; and

10 applying a high frequency voltage difference between the active electrode and a return electrode, the voltage difference being sufficient to ablate at least a portion of the disc.

1 37. The method of claim 36 further comprising introducing an
2 electrosurgical probe through an opening in the annulus of the disc, the active electrode
3 being positioned on an active side of the electrosurgical probe.

1 38. A method of performing spinal surgery, the method comprising:
2 positioning an electrosurgical instrument in close proximity to a spinal disc,
3 the instrument having an active electrode and a return electrode;

4 delivering an electrically conductive fluid toward a distal tip of the
5 electrosurgical instrument;

6 delivering a high frequency electrical energy to the active electrode such that
7 the conductive fluid completes a current flow path between the active electrode and the
8 return electrode; and

9 aspirating the conductive fluid through an aspiration lumen, wherein a distal
10 end of the aspiration lumen is positioned proximal of the return electrode.

1 39. The method of claim 38 wherein the distal end of the aspiration
2 lumen is spaced from the spinal disc.

1 40. The method of claim 38 further comprising reducing the size of
2 tissue that is aspirated through an aspiration lumen with an aspiration electrode.

1 41. An electrosurgical apparatus for treating tissue within a patient's
2 spine, the apparatus comprising:

3 a shaft comprising a distal end portion that comprises an active side and a
4 non-active side, wherein the shaft defines a longitudinal axis;

5 at least one active electrode positioned on the active side of the distal end
6 portion of the shaft,

7 an insulator disposed on the non-active side of the distal end portion of the
8 shaft, the insulator being positioned to insulate a dura mater of the spine from the active
9 electrode;

10 a return electrode; and

11 a high frequency voltage source which creates a voltage difference between
12 the active electrode and the return electrode to treat the tissue.

1 42. The apparatus of claim 41 wherein the active electrode extends
2 substantially orthogonal to the longitudinal axis of the shaft;

3 43. The apparatus of claim 41 wherein the active electrode comprises an
4 electrode array disposed near the distal end of the shaft, the array including a plurality of
5 electrically isolated active electrodes disposed over a contact surface.

1 44. The apparatus of claim 41 wherein the distal end portion of the shaft
2 is curved or bent.

1 45. The apparatus of claim 41 wherein the insulator is positioned
2 substantially opposite of the active electrode.

1 46. The apparatus of claim 41 further comprising a fluid delivery
2 element defining a fluid path in electrical contact with the return electrode and the active
3 electrode to generate a current flow path between the return electrode and the active
4 electrode.

1 47. The apparatus of claim 41 wherein the high frequency voltage is
2 sufficient to ablate a portion of the nucleus pulposus within the disc.

1 48. The apparatus of claim 41 to contract collagen fibers within the
2 nucleus pulposus within the disc.

1 49. The apparatus of claim 41 further comprising an electrically
2 insulating support member extending from the distal end portion of the shaft, the active
3 electrode being mounted to the support member.

1 50. An apparatus for performing spinal surgery, the apparatus
2 comprising:

3 a shaft defining a distal end portion;

4 at least one active electrode positioned on the distal end portion of the shaft;

5 a return electrode positioned proximal of the active electrode;

6 a fluid delivery lumen that delivers a conductive fluid to a point distal of the
7 return electrode;

8 a high frequency energy source configured to create a voltage difference

9 between the active electrode and return electrode; and

10 an aspiration lumen comprising an opening positioned proximal of the return
11 electrode, wherein the aspiration lumen is configured to aspirate the conductive fluid over
12 the return electrode so as to complete the complete a current flow path between the active
13 electrode and the return electrode.

1 51. The apparatus of claim 50 wherein the fluid delivery lumen and the
2 aspiration lumen are semi-annular shaped.

1 52. The apparatus of claim 50 wherein the fluid delivery lumen and the
2 aspiration lumen extend around the shaft.

1 53. An apparatus for treating intervertebral discs, the apparatus

2 comprising:

3 a steerable shaft defining a distal end portion, wherein the distal end portion
4 of the steerable shaft is moveable to a curved configuration that approximates the curvature
5 of the inner surface of an annulus fibrosus;

6 at least one active electrode positioned on the distal end portion of the shaft;

7 a return electrode positioned proximal of the active electrode; and

8 a high frequency energy source configured to create a voltage difference

9 between the active electrode and return electrode.

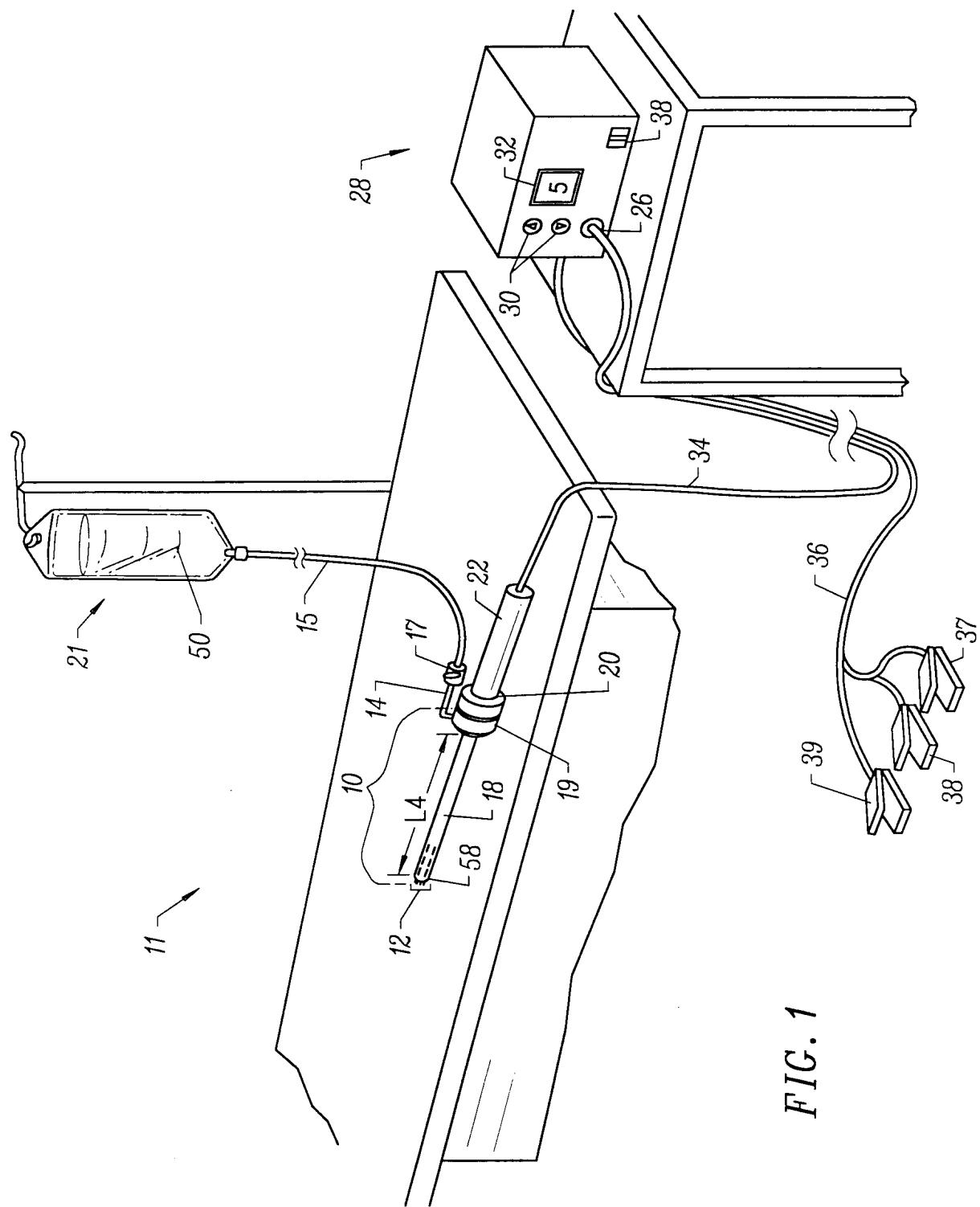
1 54. The apparatus of claim 53 further comprising a fluid delivery lumen
2 configured to deliver a conductive fluid to the active electrode.

1 55. The apparatus of claim 53 further comprising an aspiration lumen
2 adapted to aspirate the conductive fluid adjacent the active electrode.

1 56. The apparatus of claim 53, further comprising a coagulation
2 electrode coupled to the high frequency energy source.

1 57. The apparatus of claim 56, wherein the high frequency voltage
2 source is configured to deliver a high frequency voltage to the coagulation electrode that is
3 insufficient to ablate tissue.

1/54



2/54

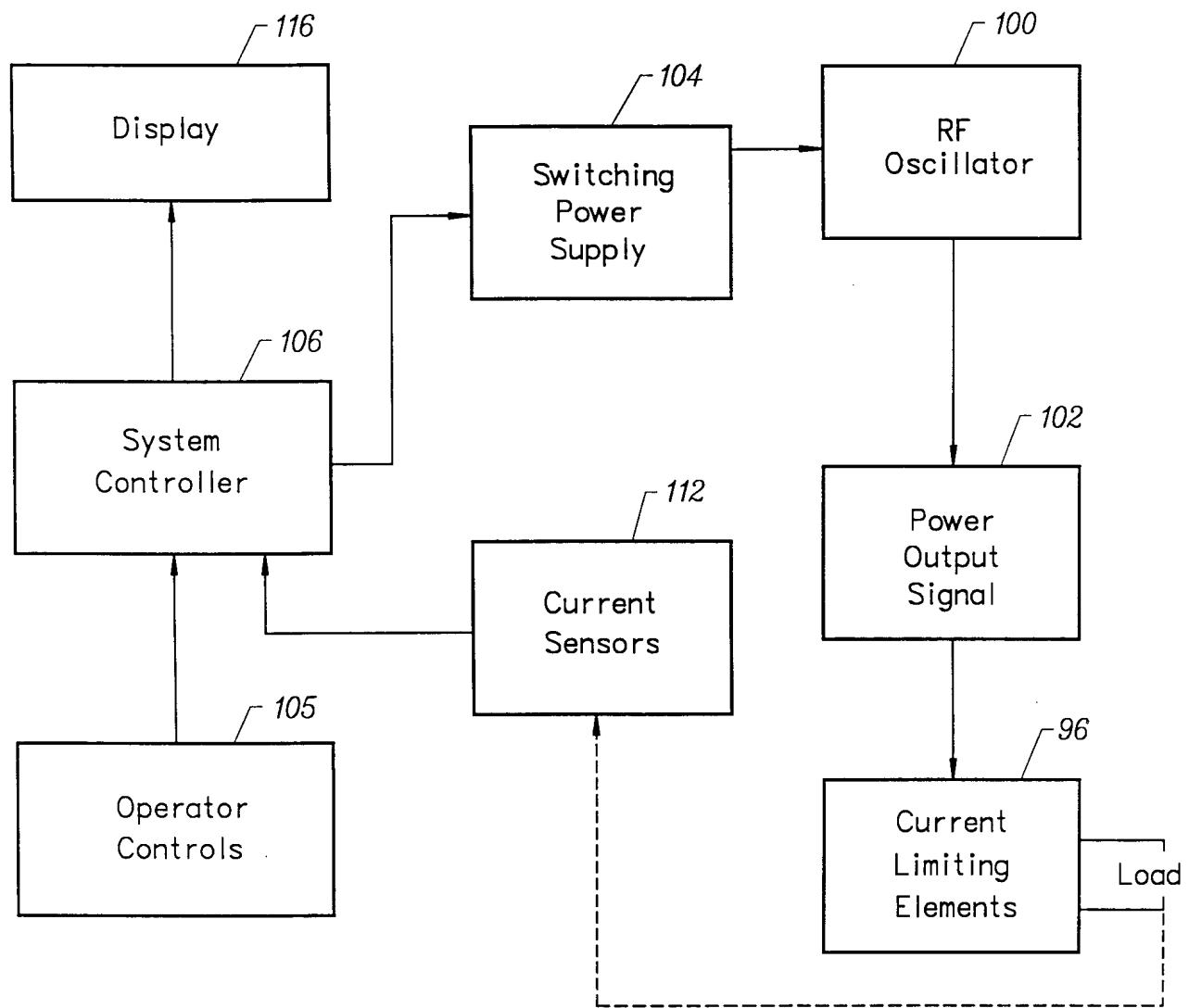
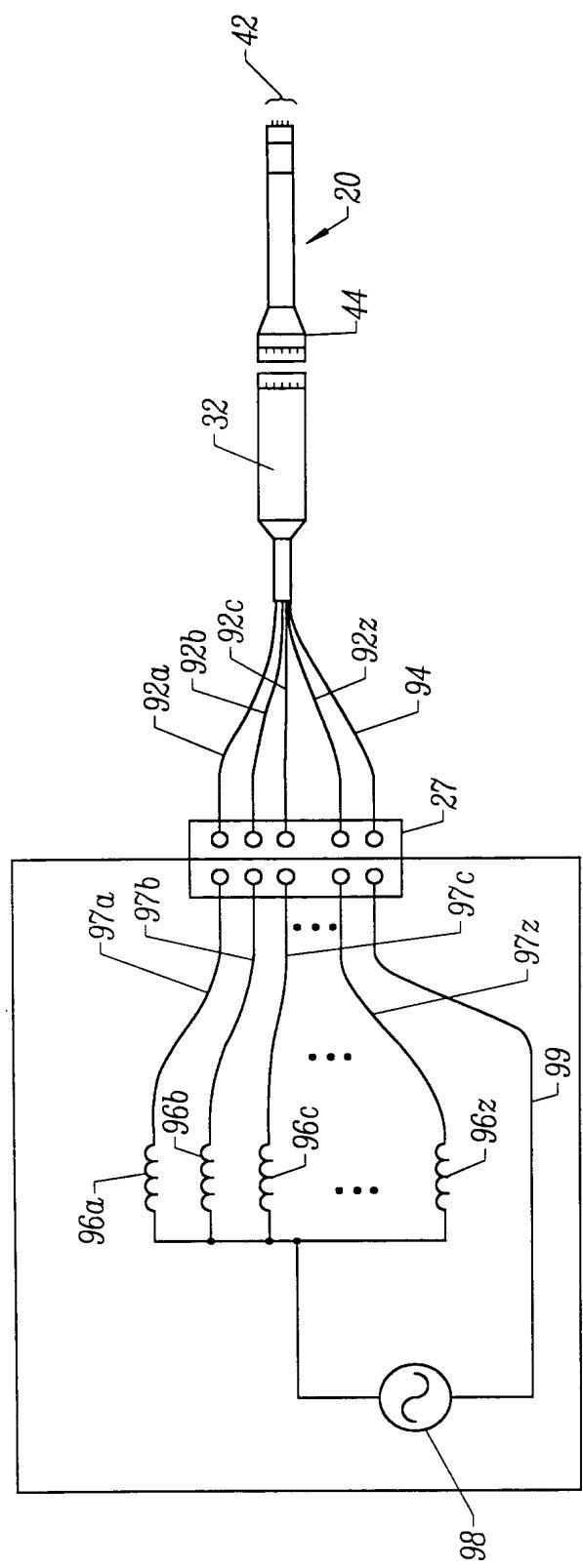


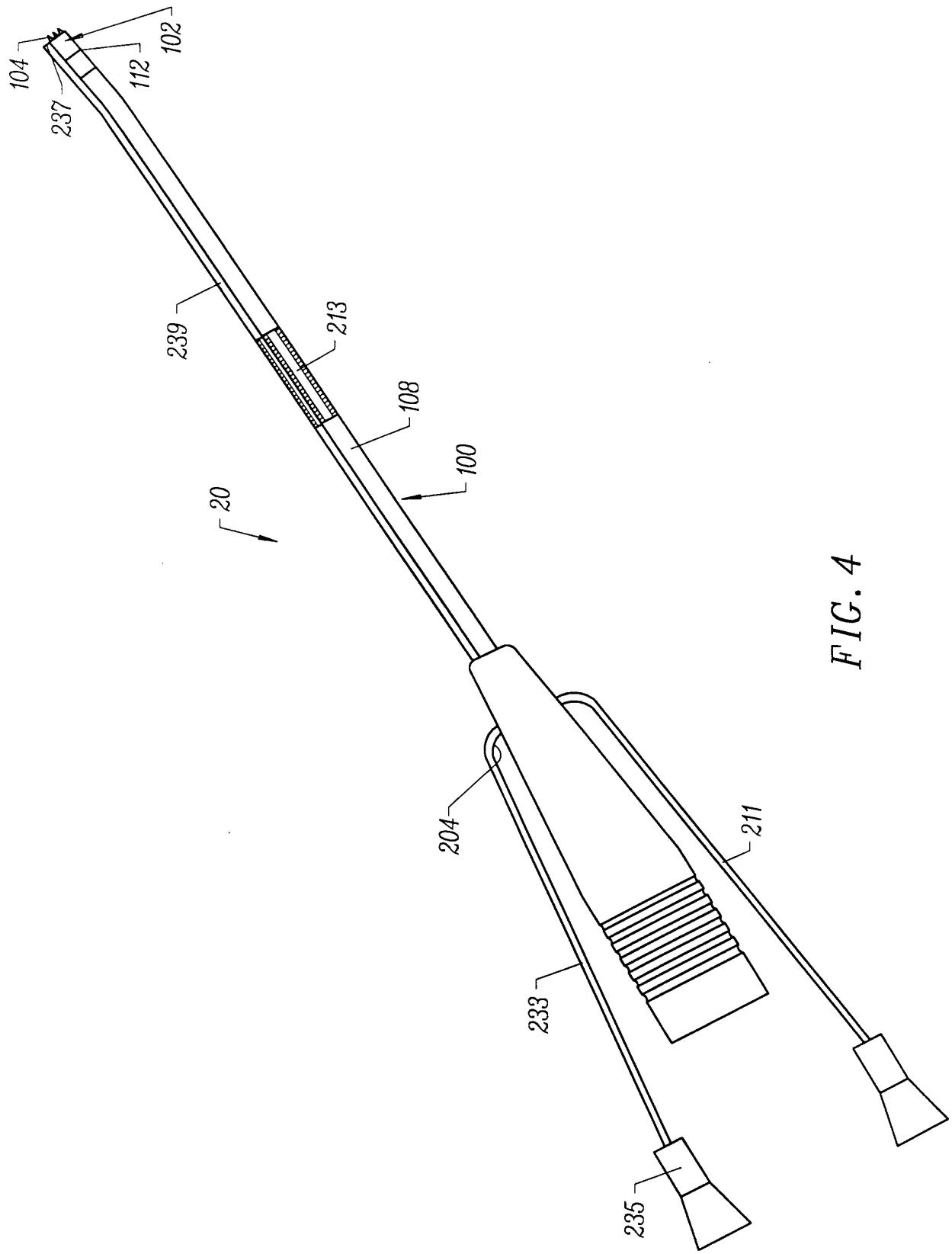
FIG. 2

3/54

FIG. 3



4/54



5/54

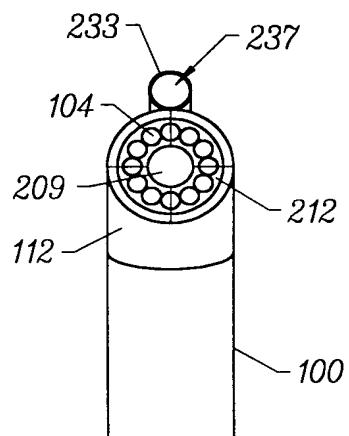


FIG. 5

6/54

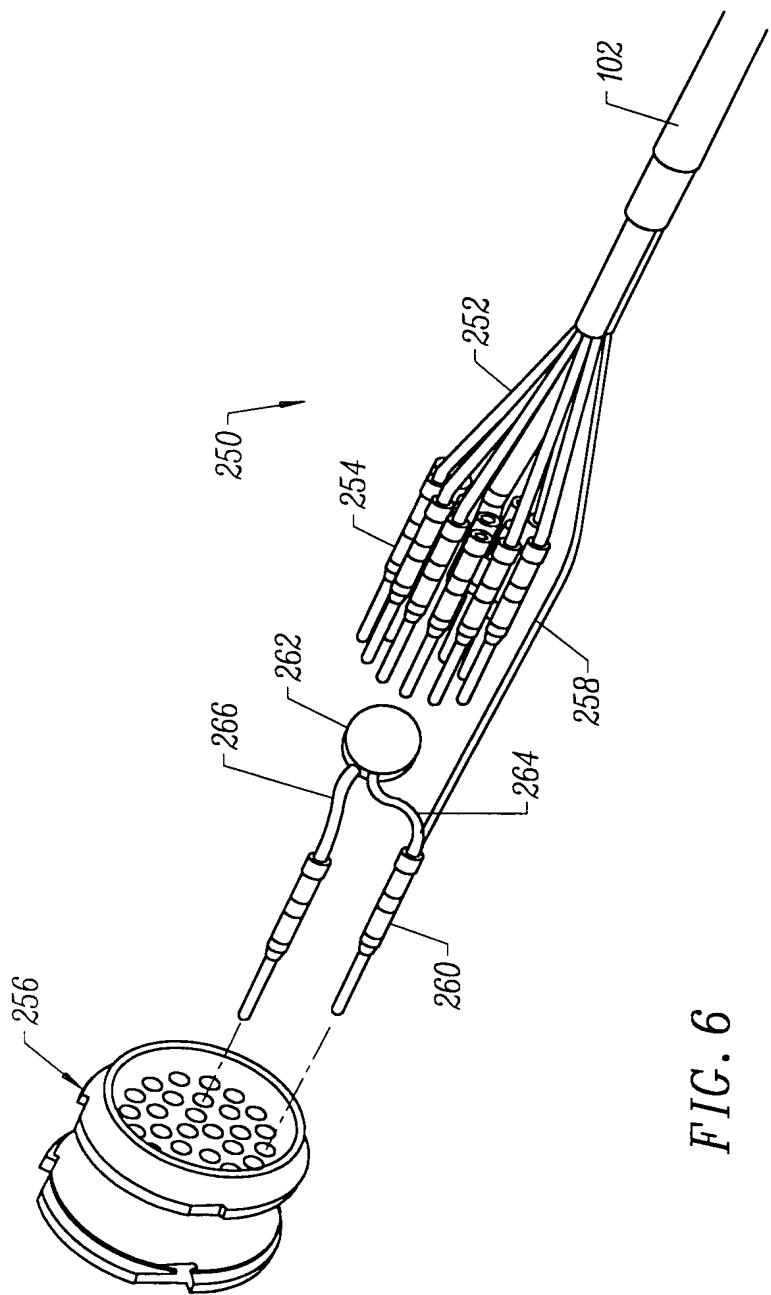


FIG. 6

7/54

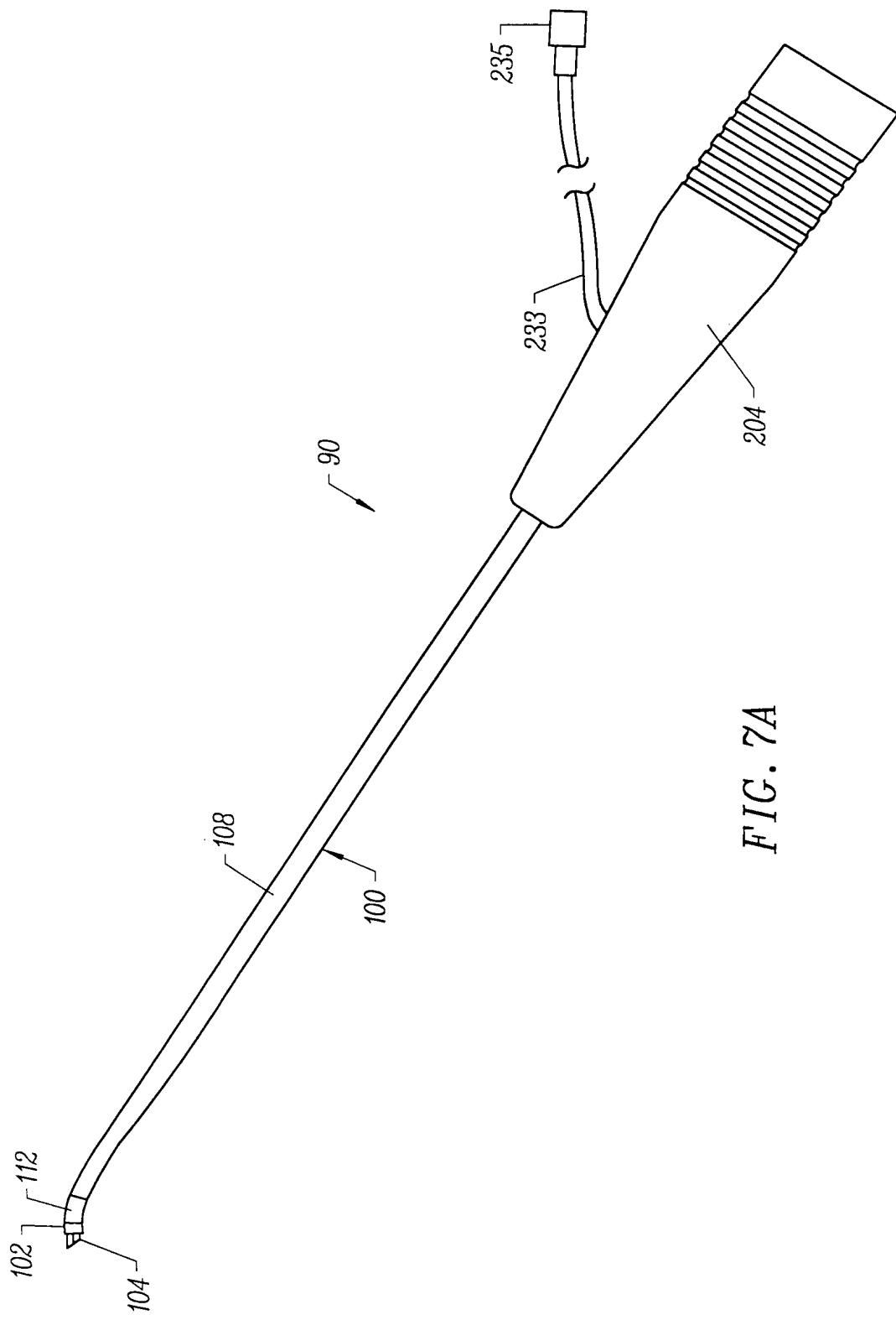


FIG. 7A

8/54

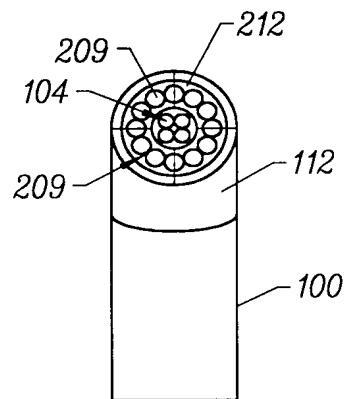


FIG. 7B

9/54

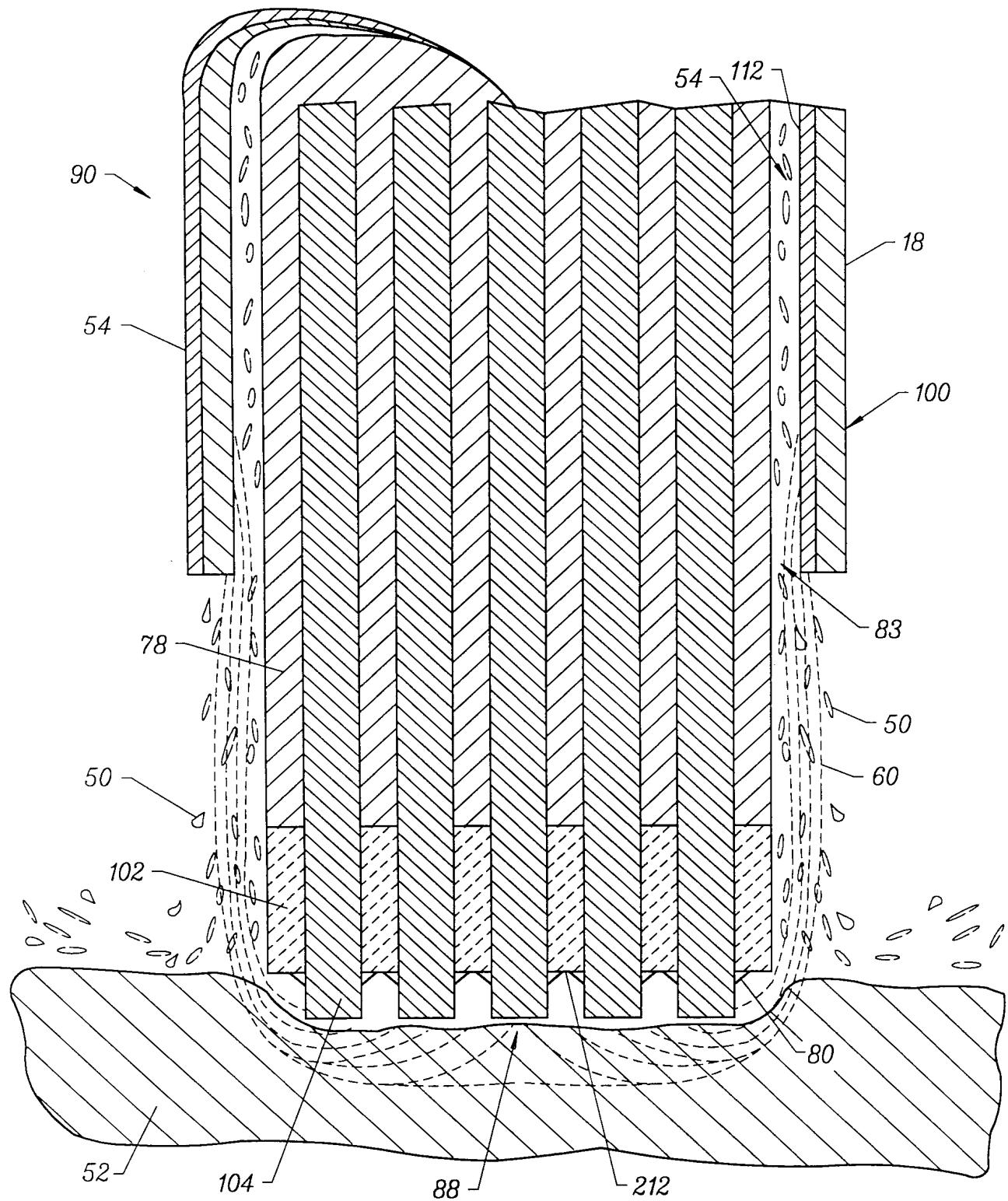


FIG. 8A

10/54

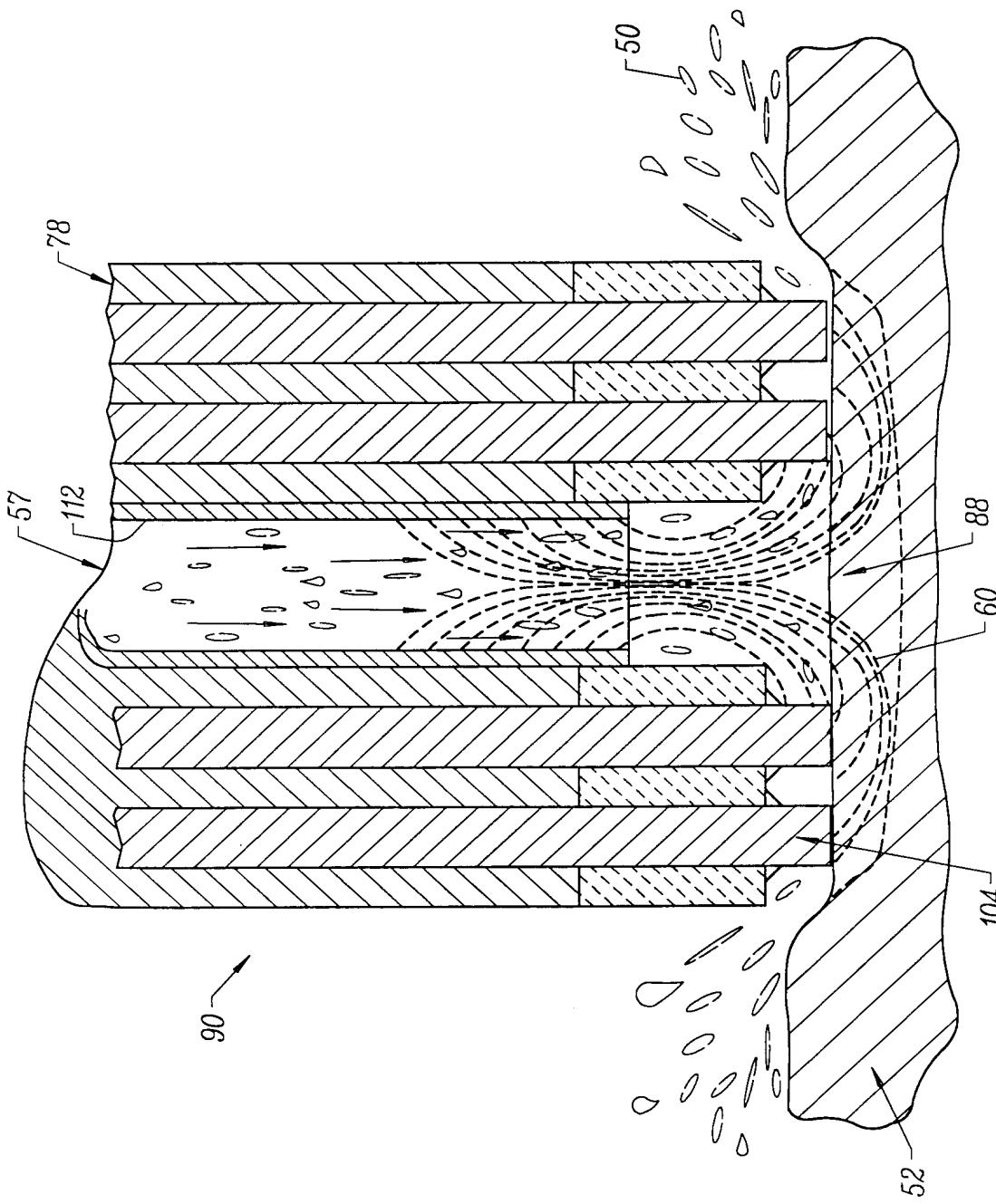


FIG. 8B

11/54

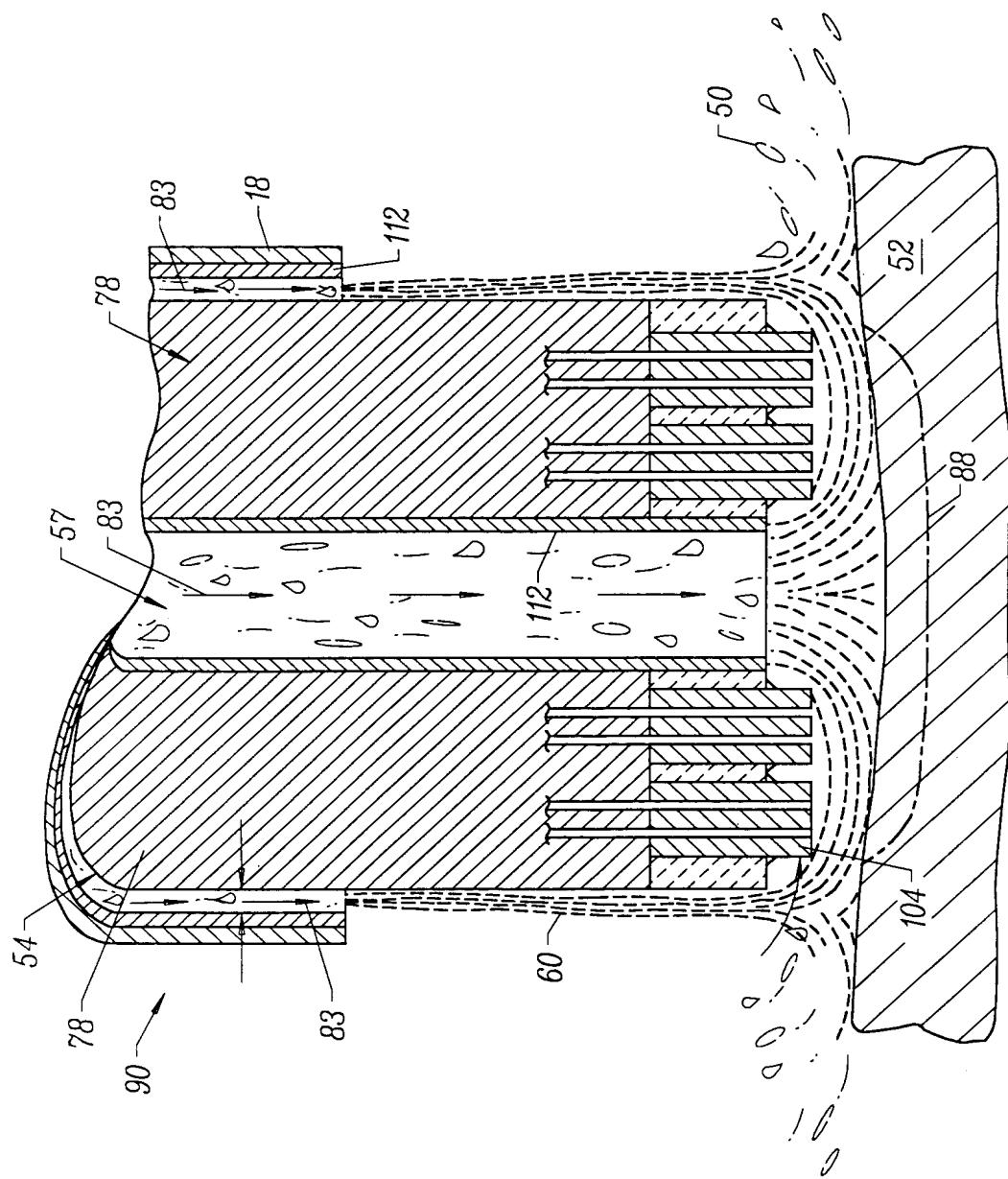


FIG. 8C

12/54

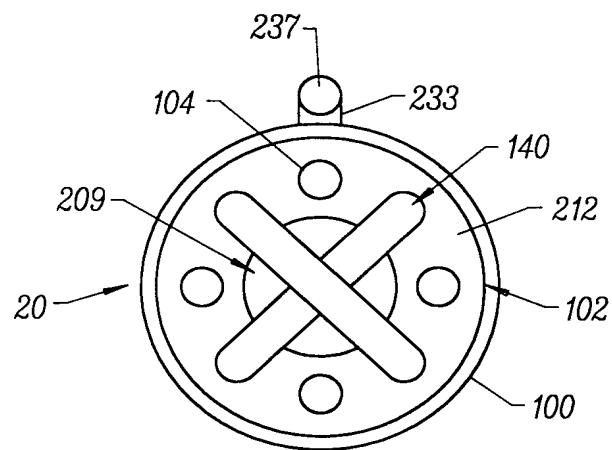


FIG. 9

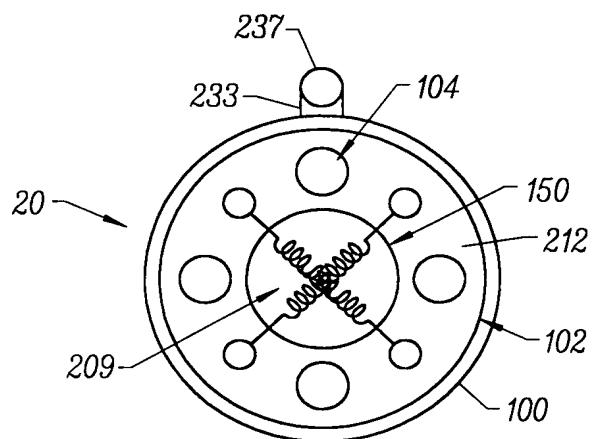


FIG. 10

13/54

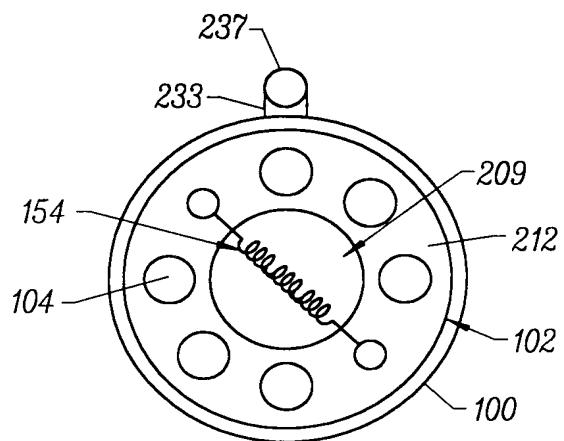


FIG. 11

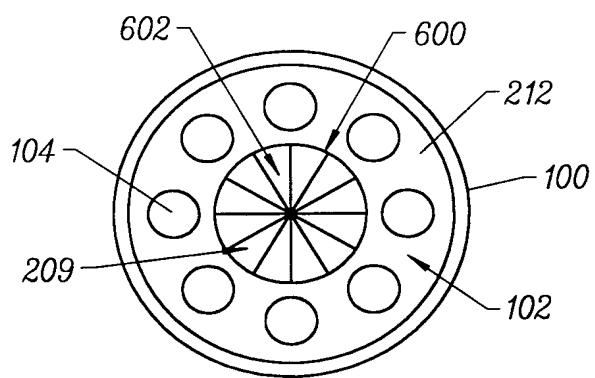


FIG. 12

14/54

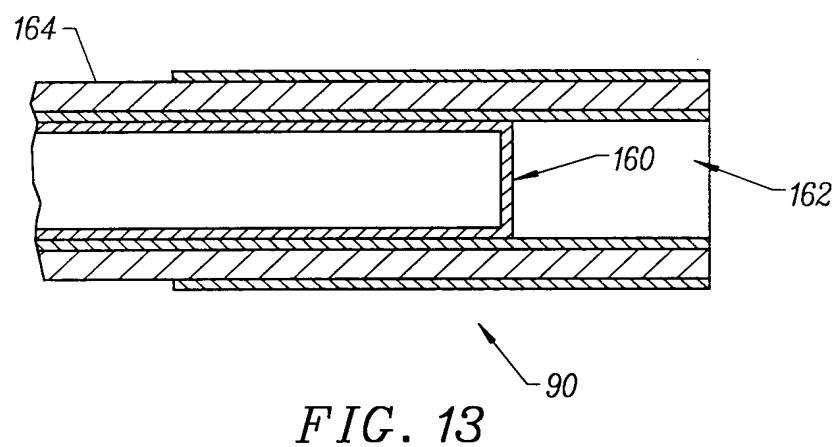


FIG. 13

15/54

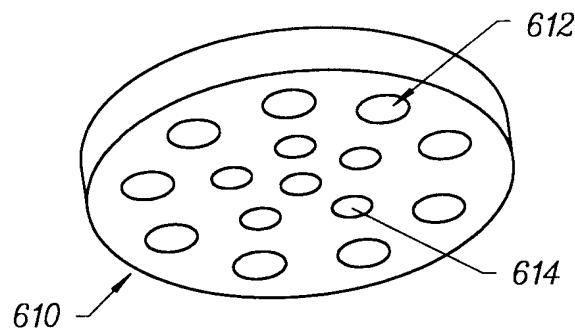


FIG. 14A

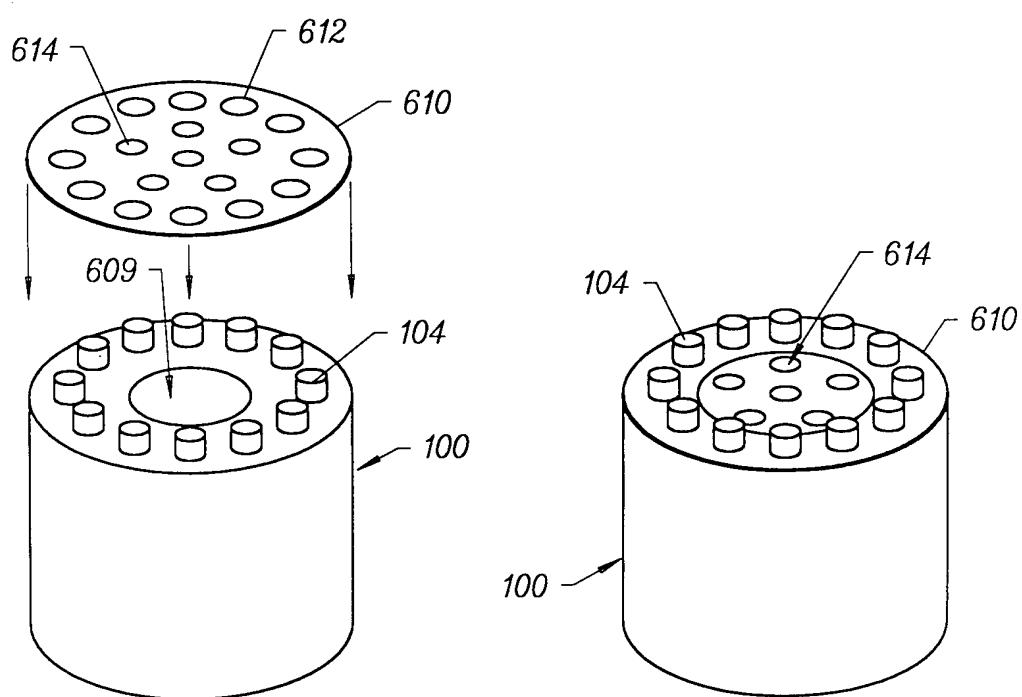


FIG. 14B

FIG. 14C

16/54

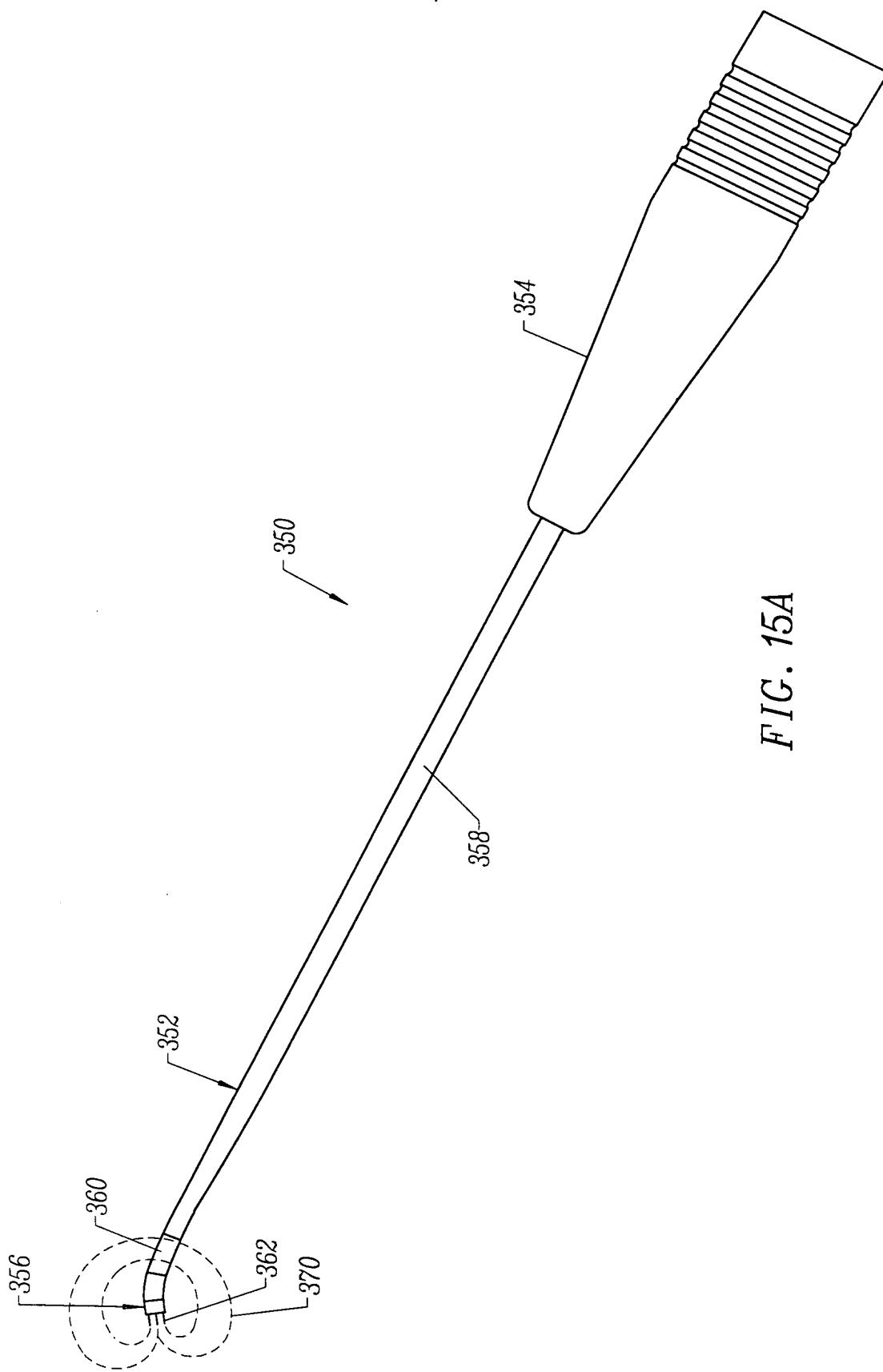


FIG. 15A

17/54

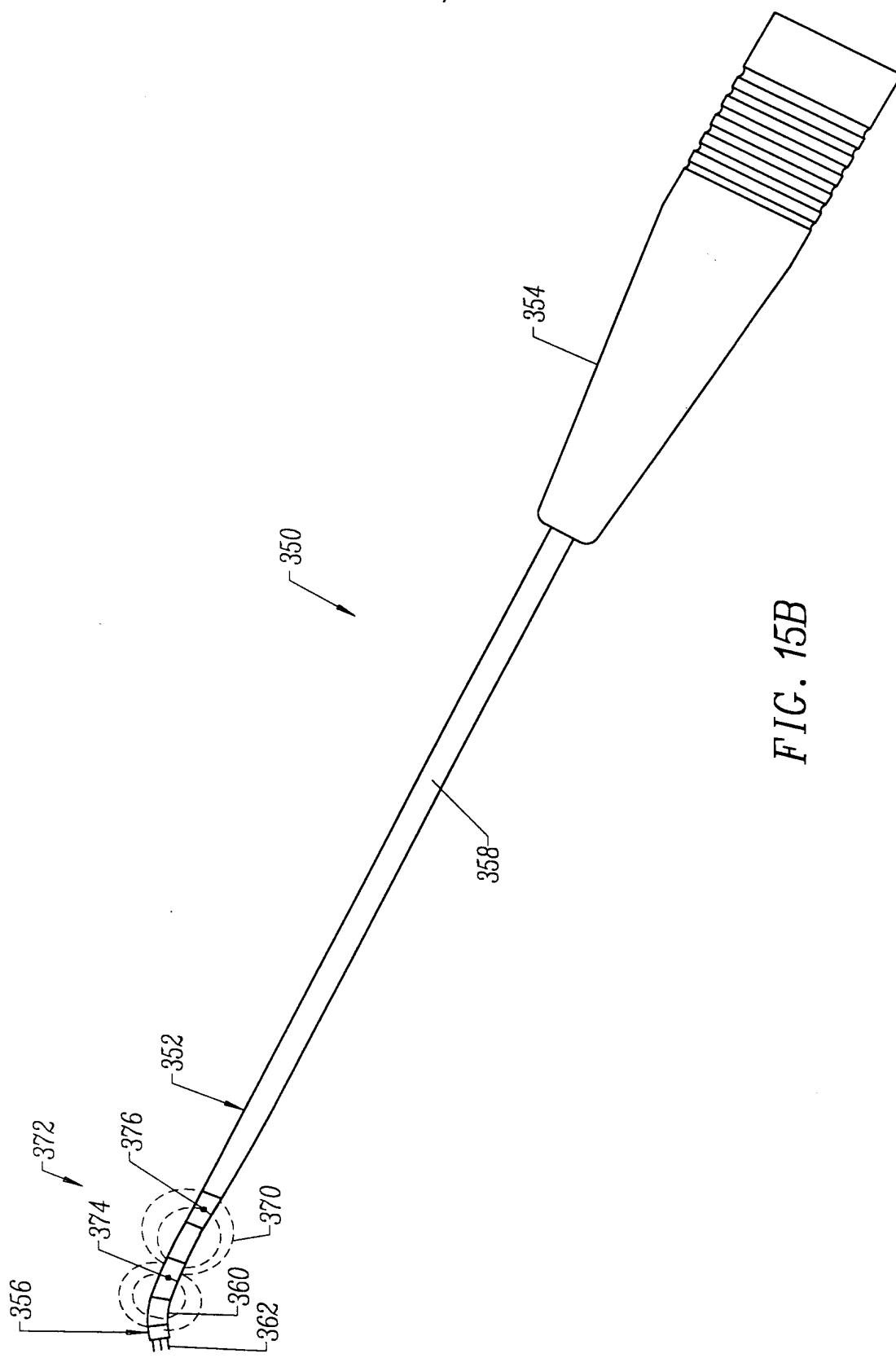


FIG. 15B

18/54

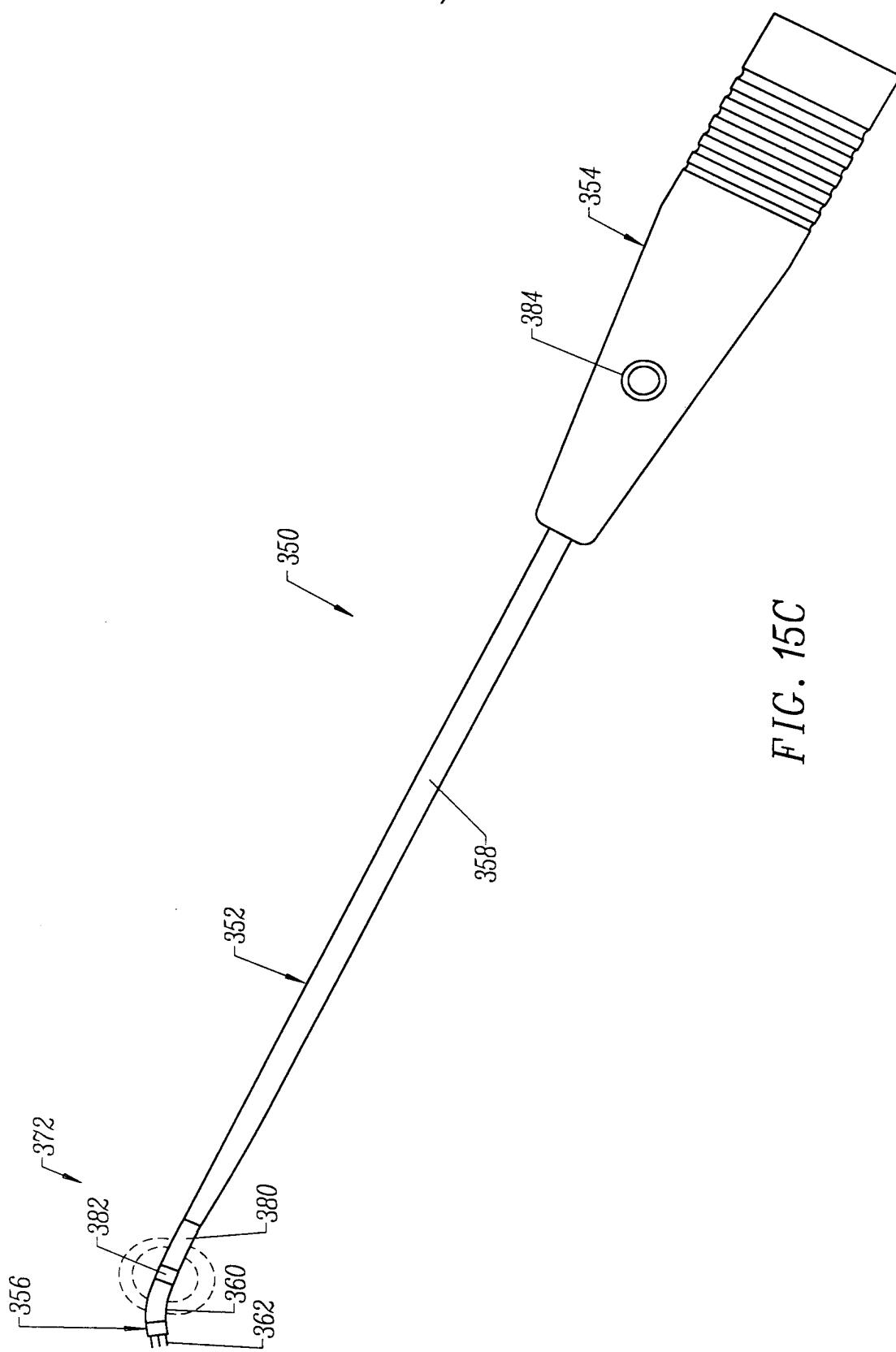


FIG. 15C

19/54

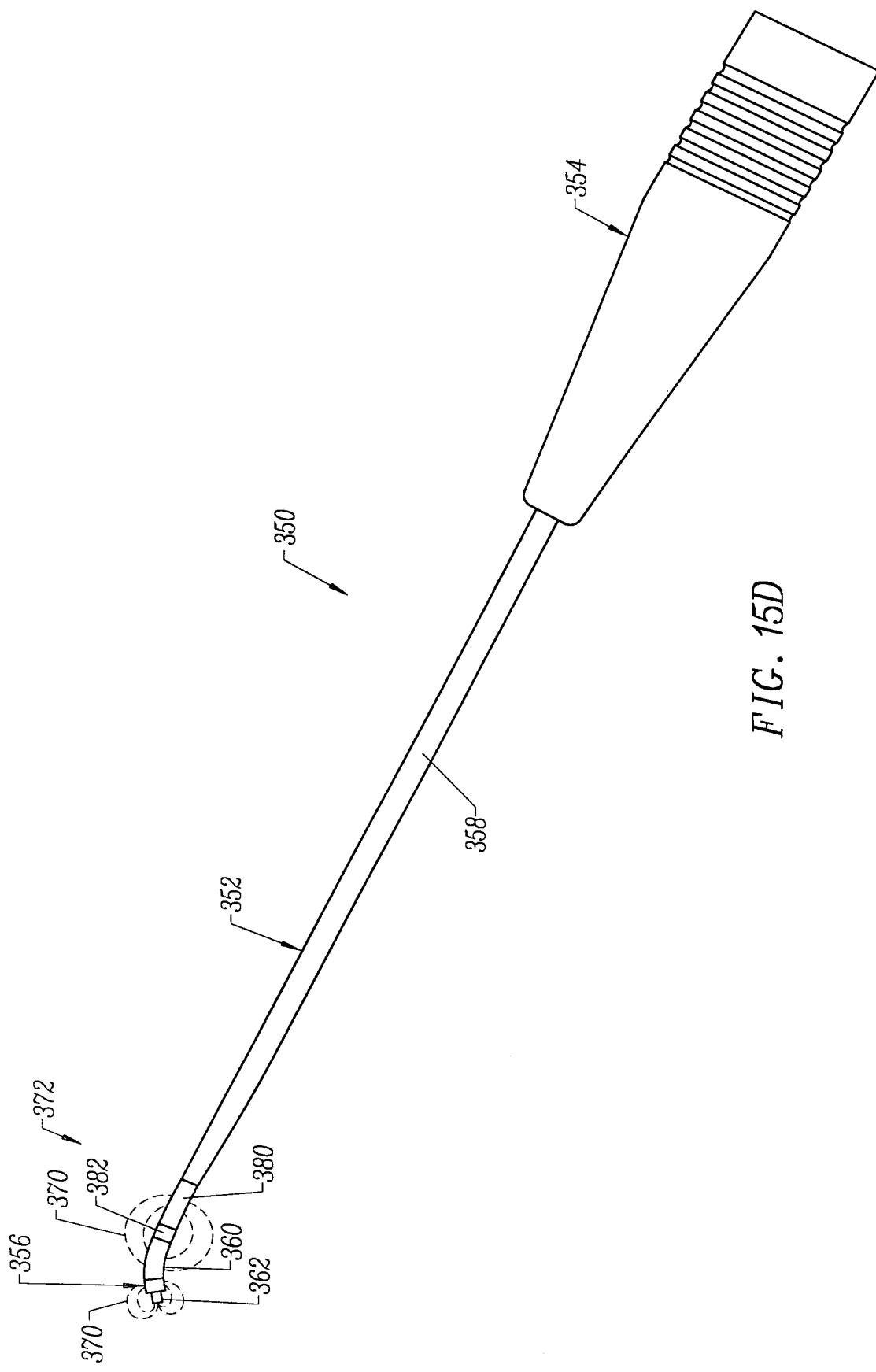


FIG. 15D

20/54

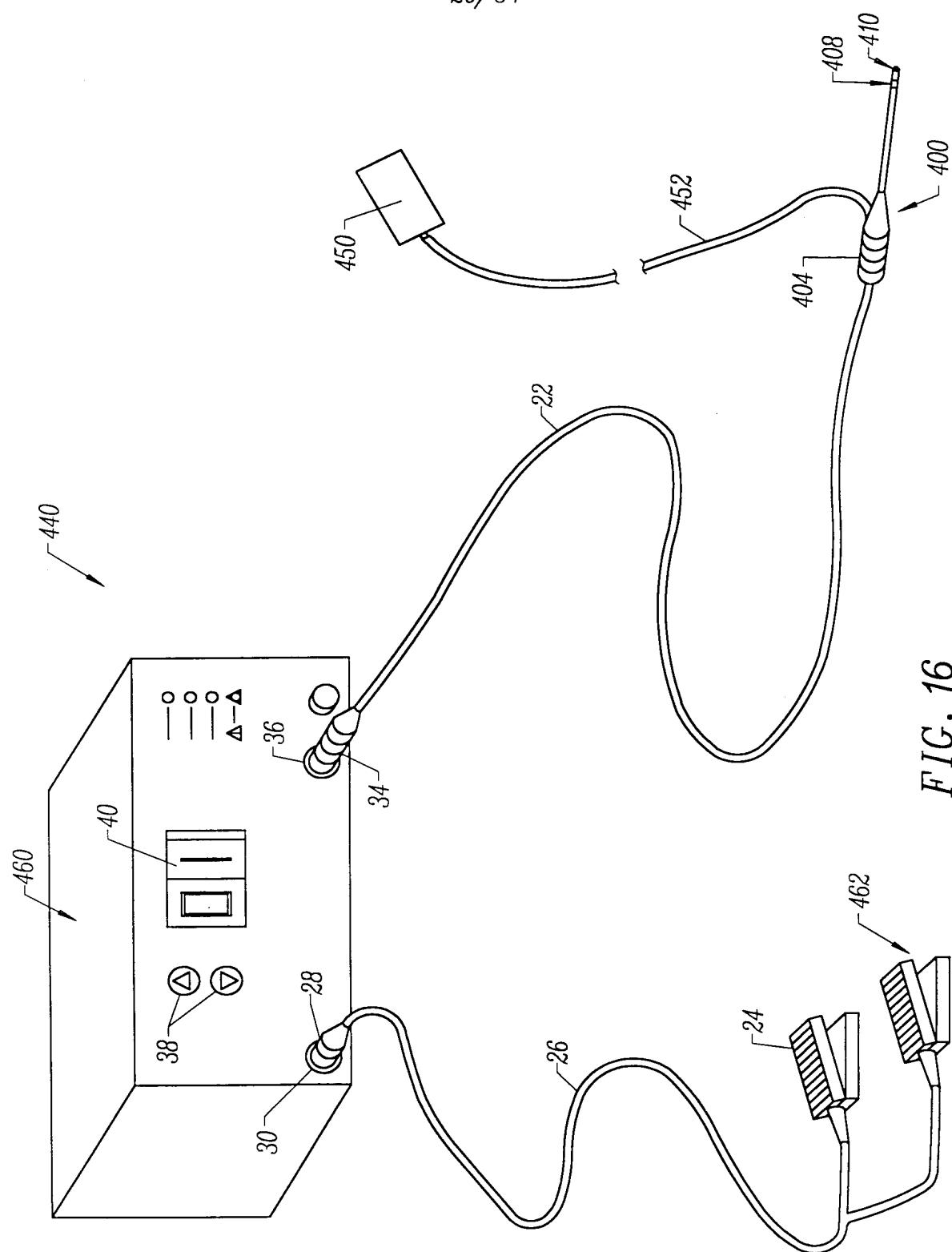


FIG. 16

21/54

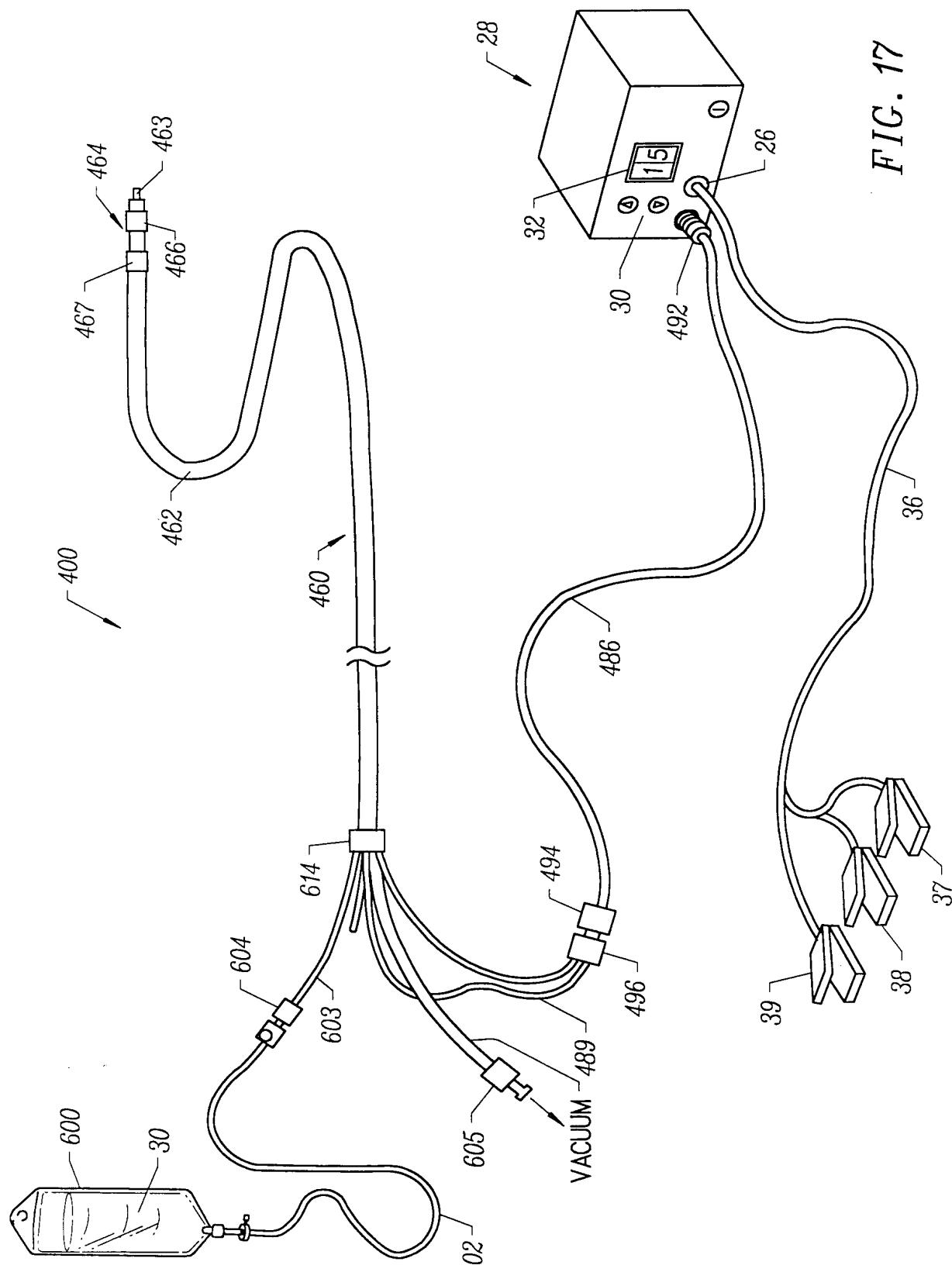


FIG. 17

22/54

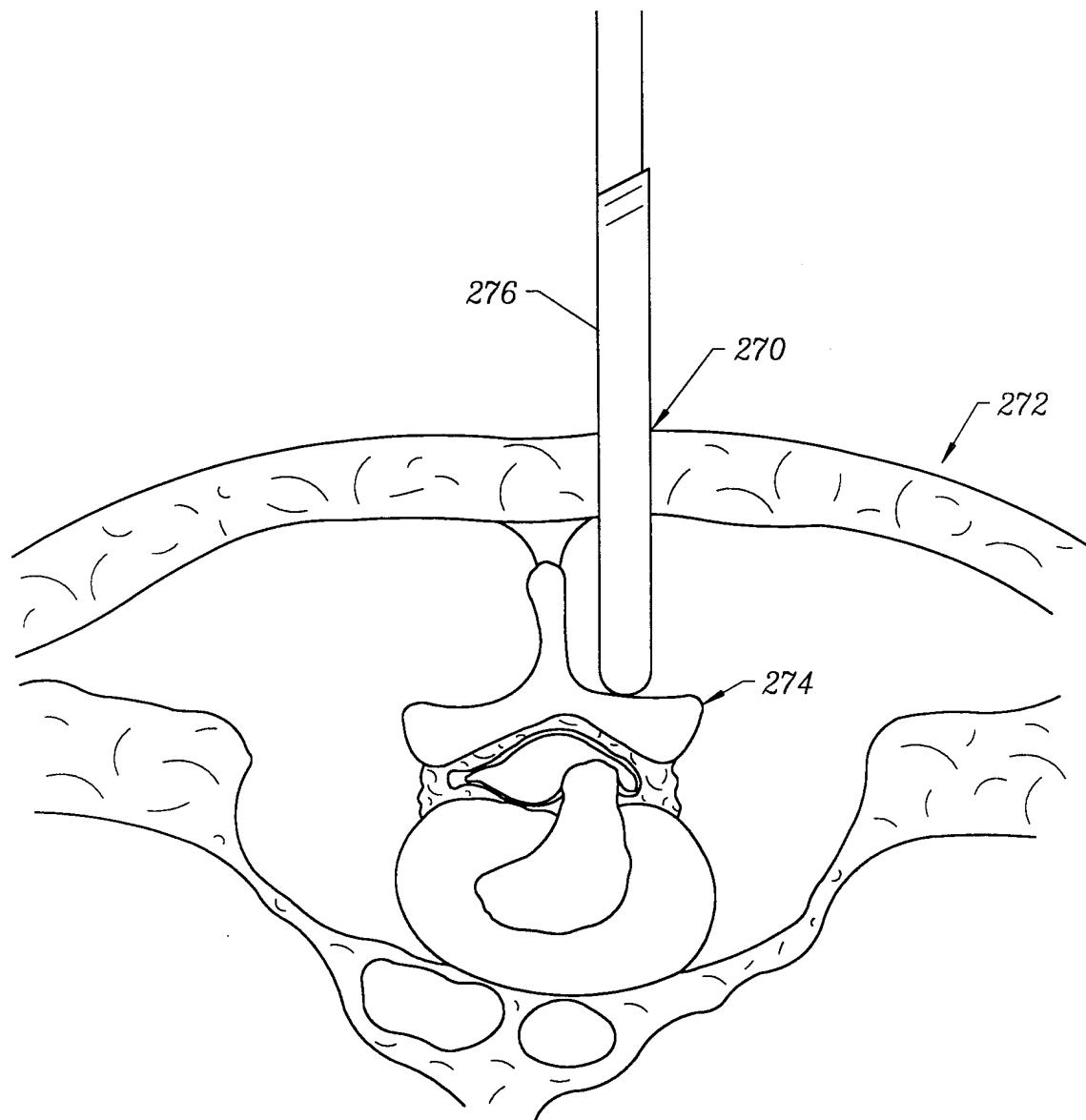


FIG. 18

23/54

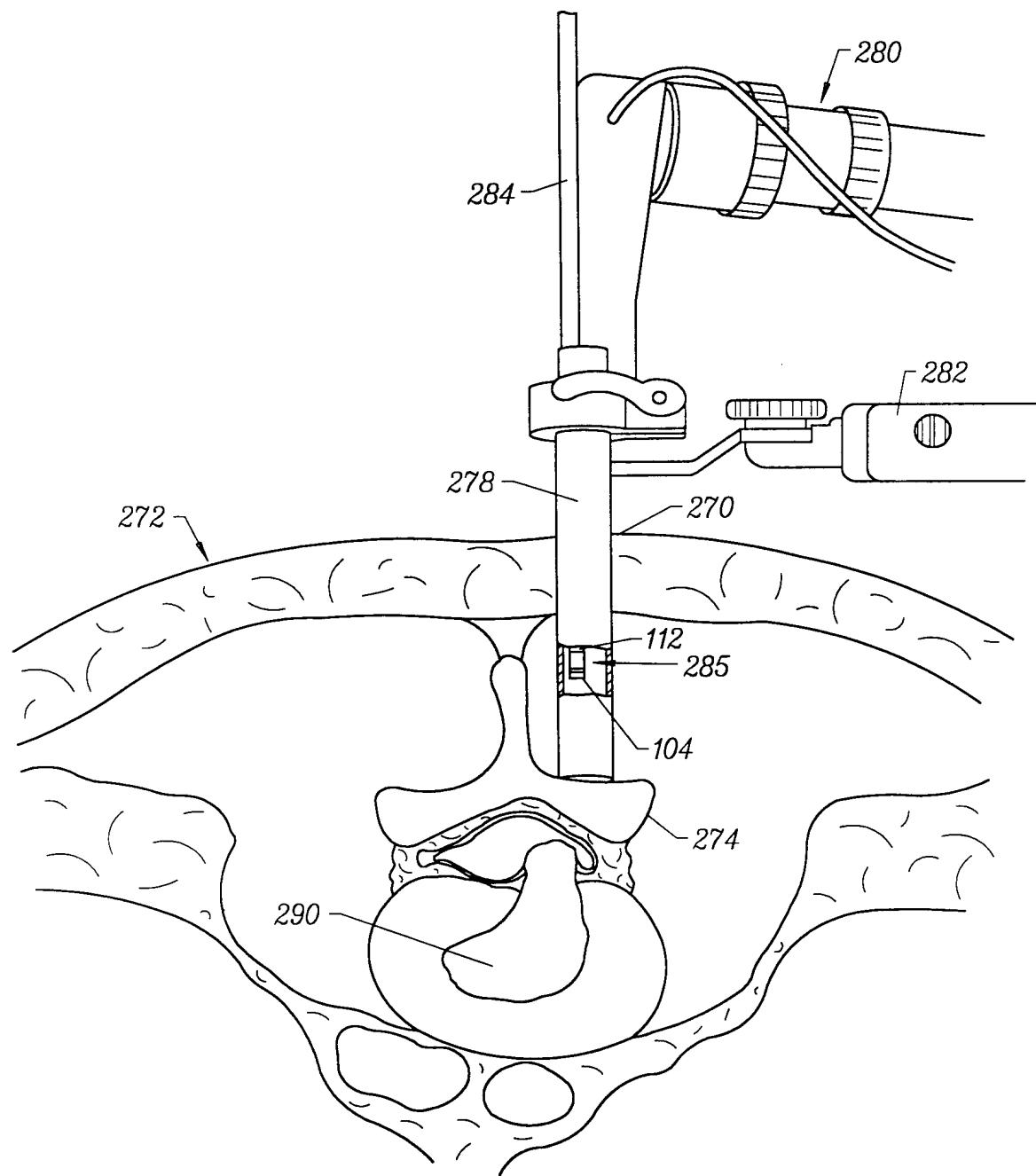


FIG. 19

24/54

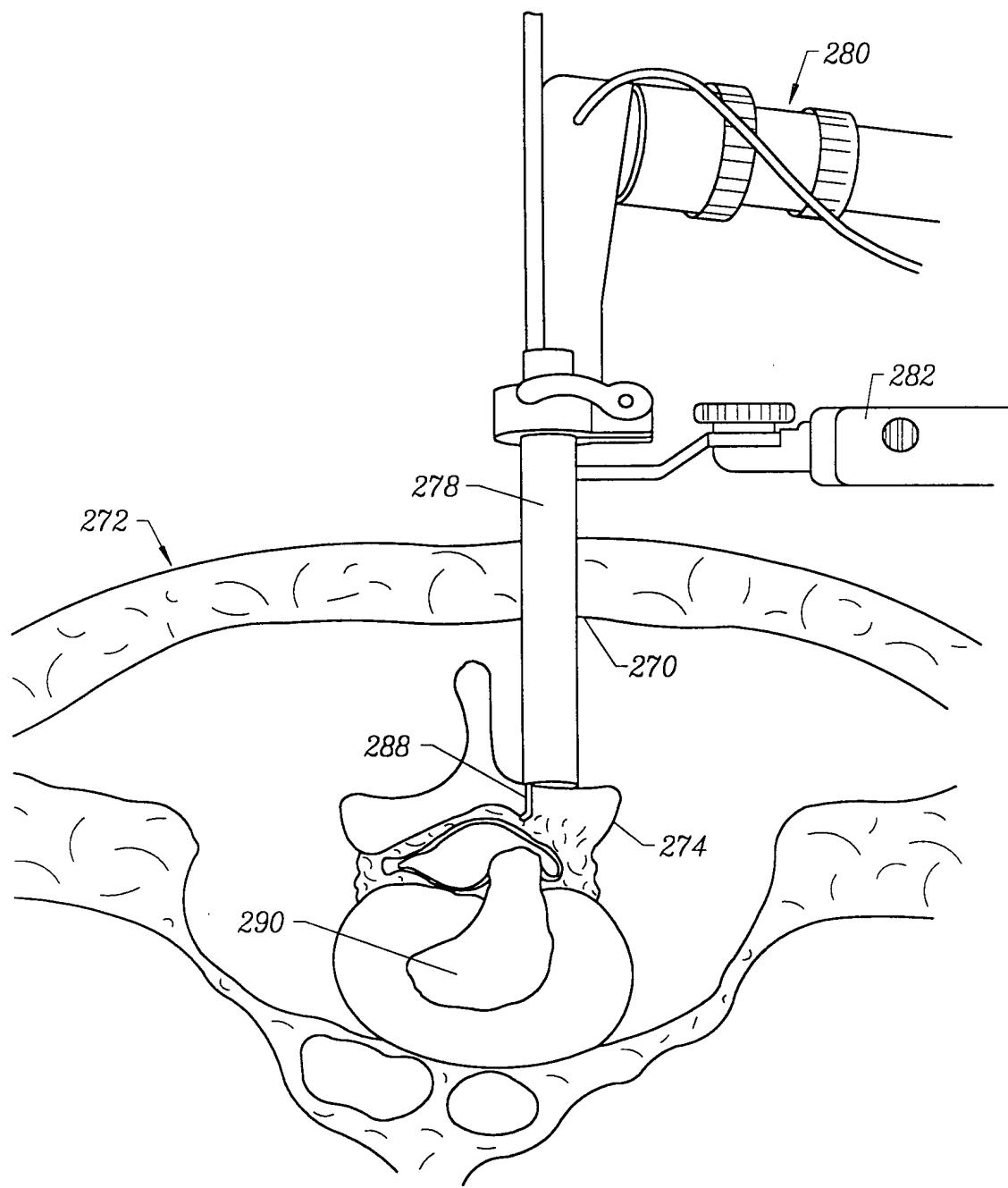


FIG. 20

25/54

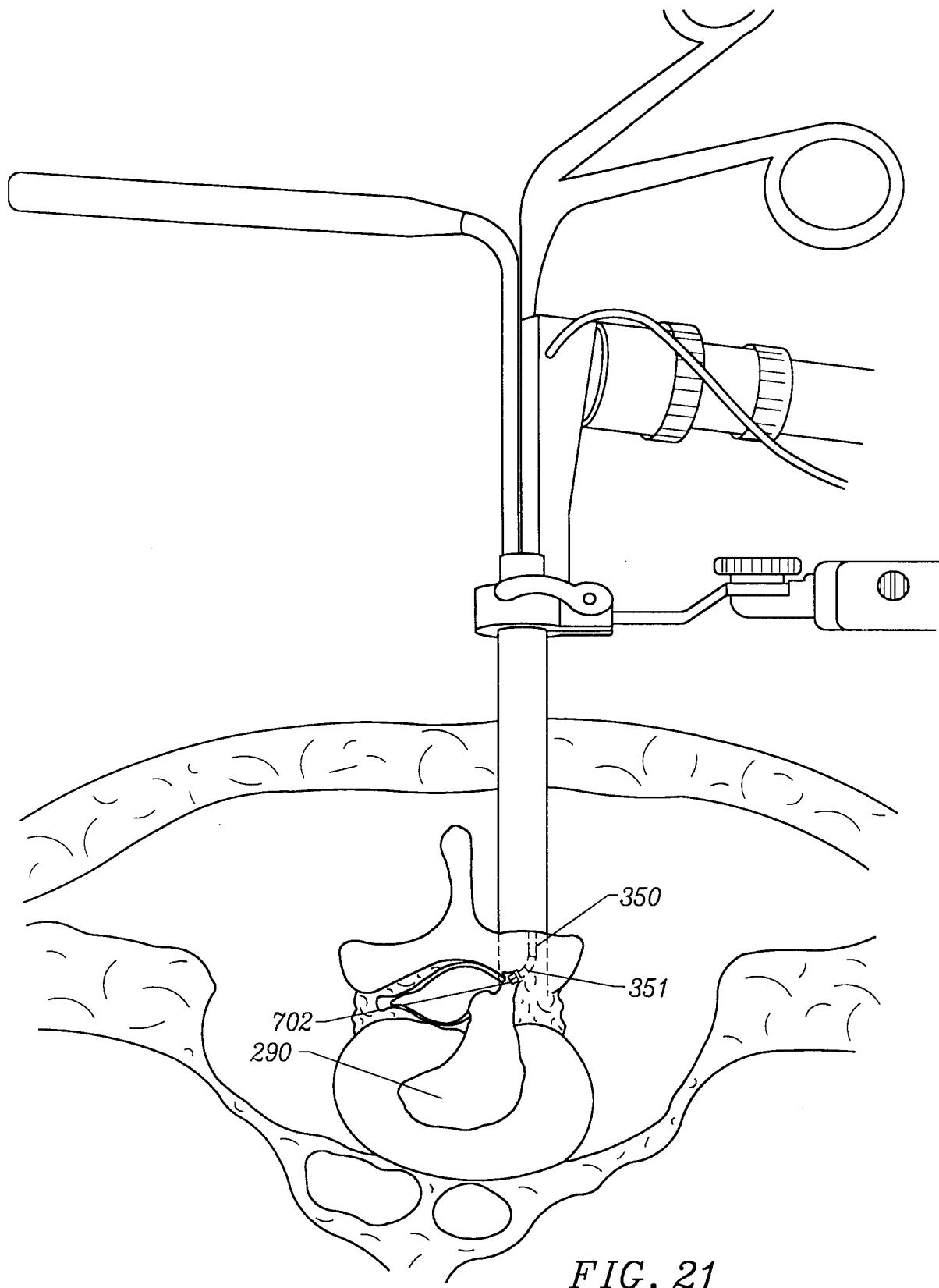


FIG. 21

26/54

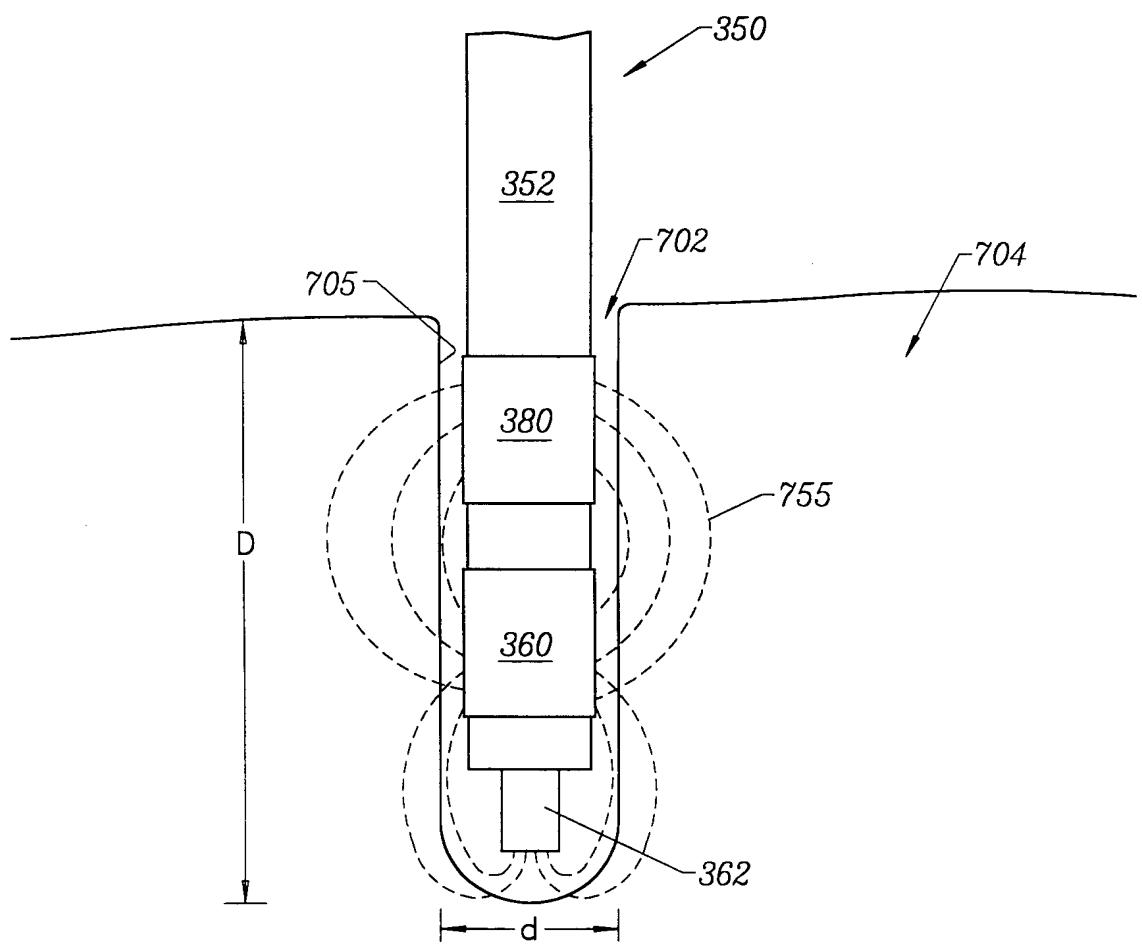


FIG. 22

27/54

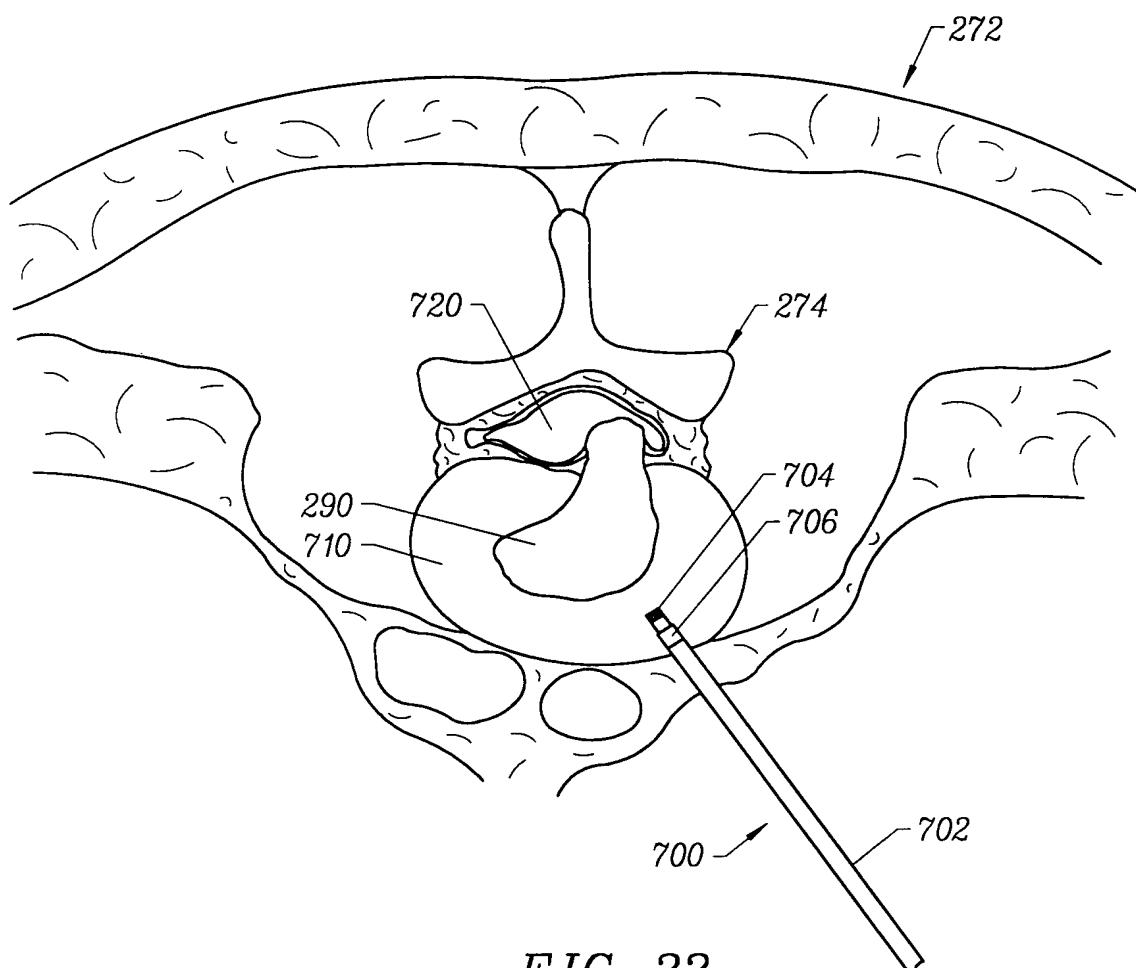


FIG. 23

28/54

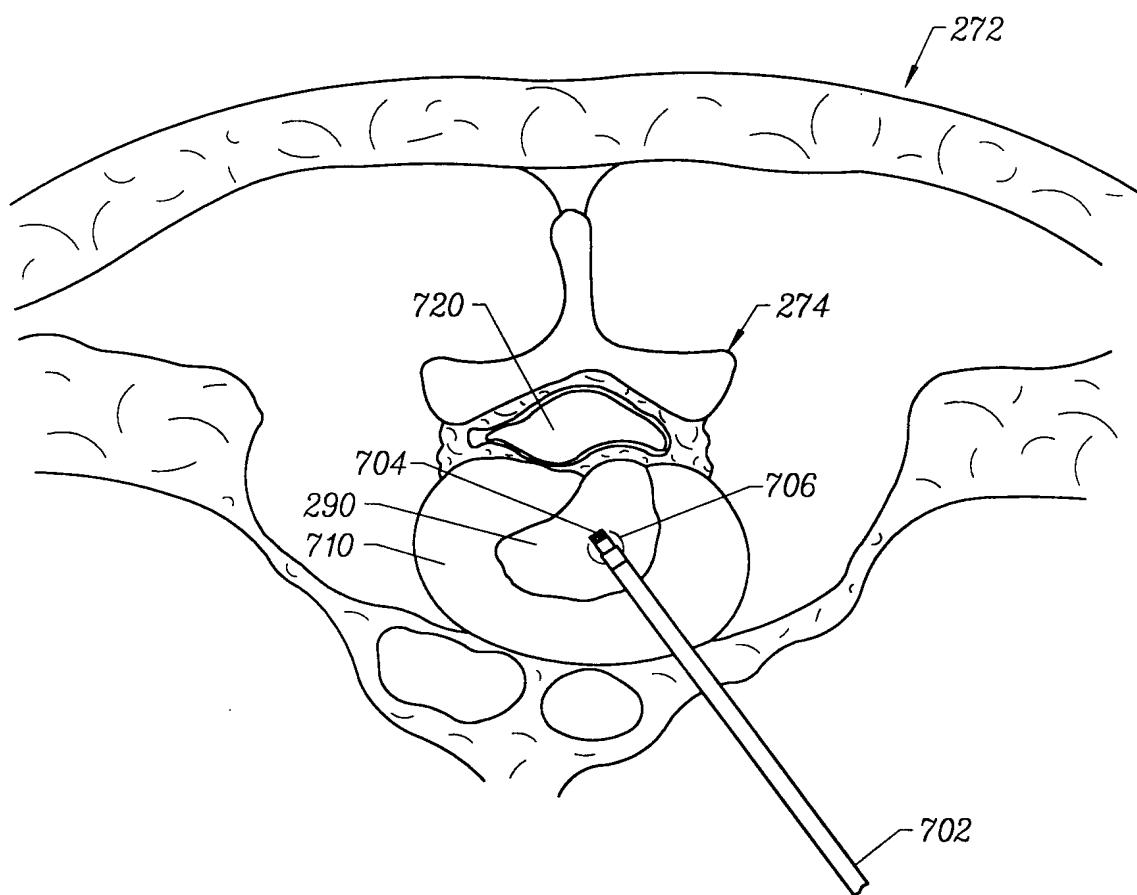


FIG. 24

29/54

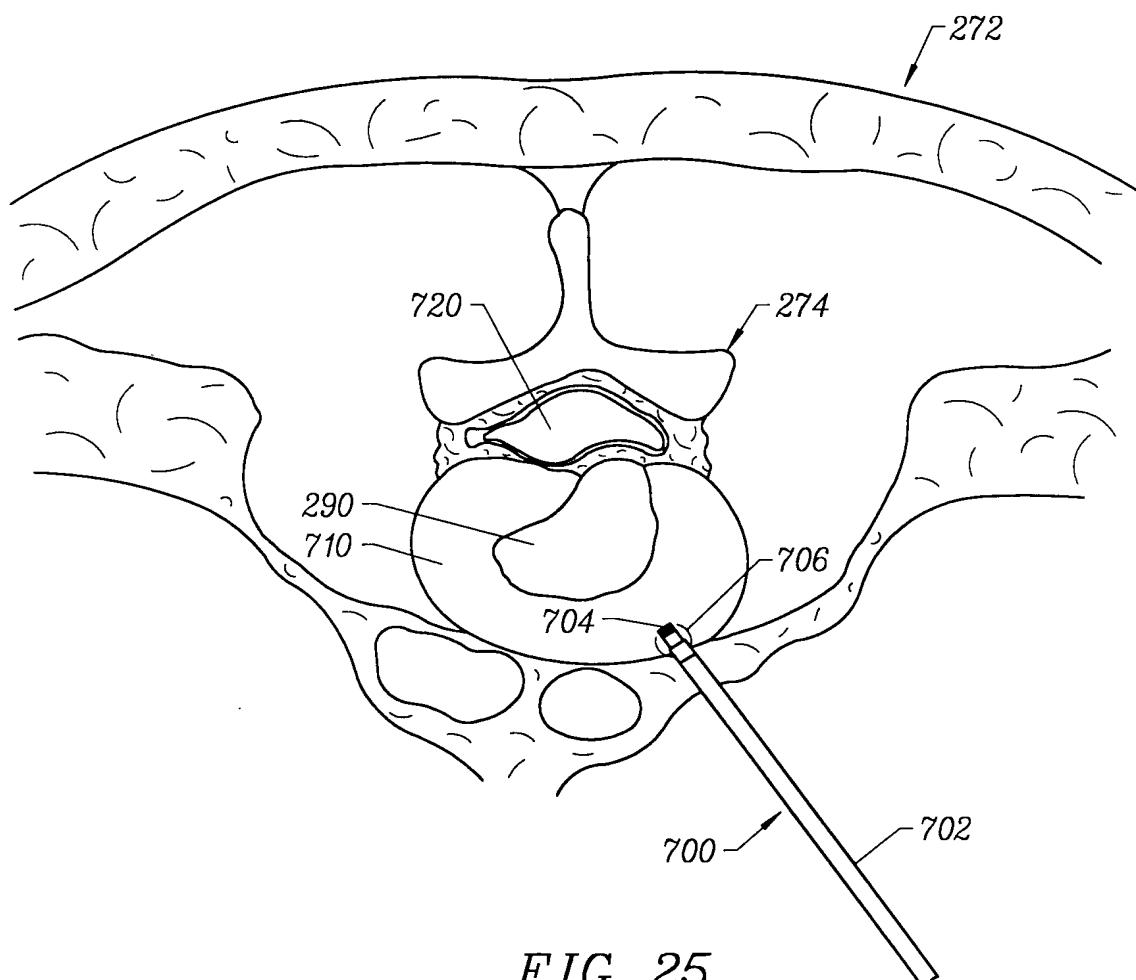


FIG. 25

30/54

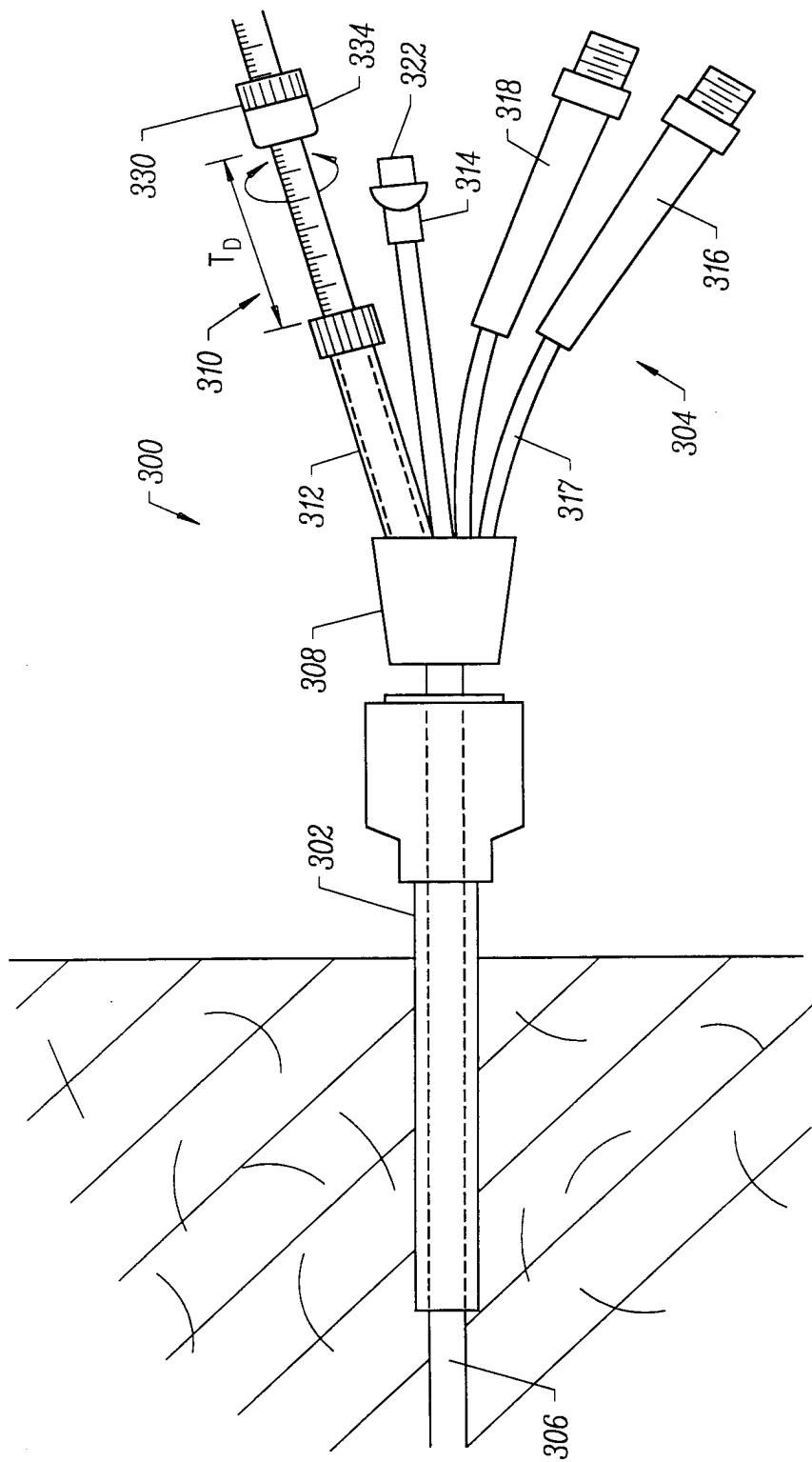
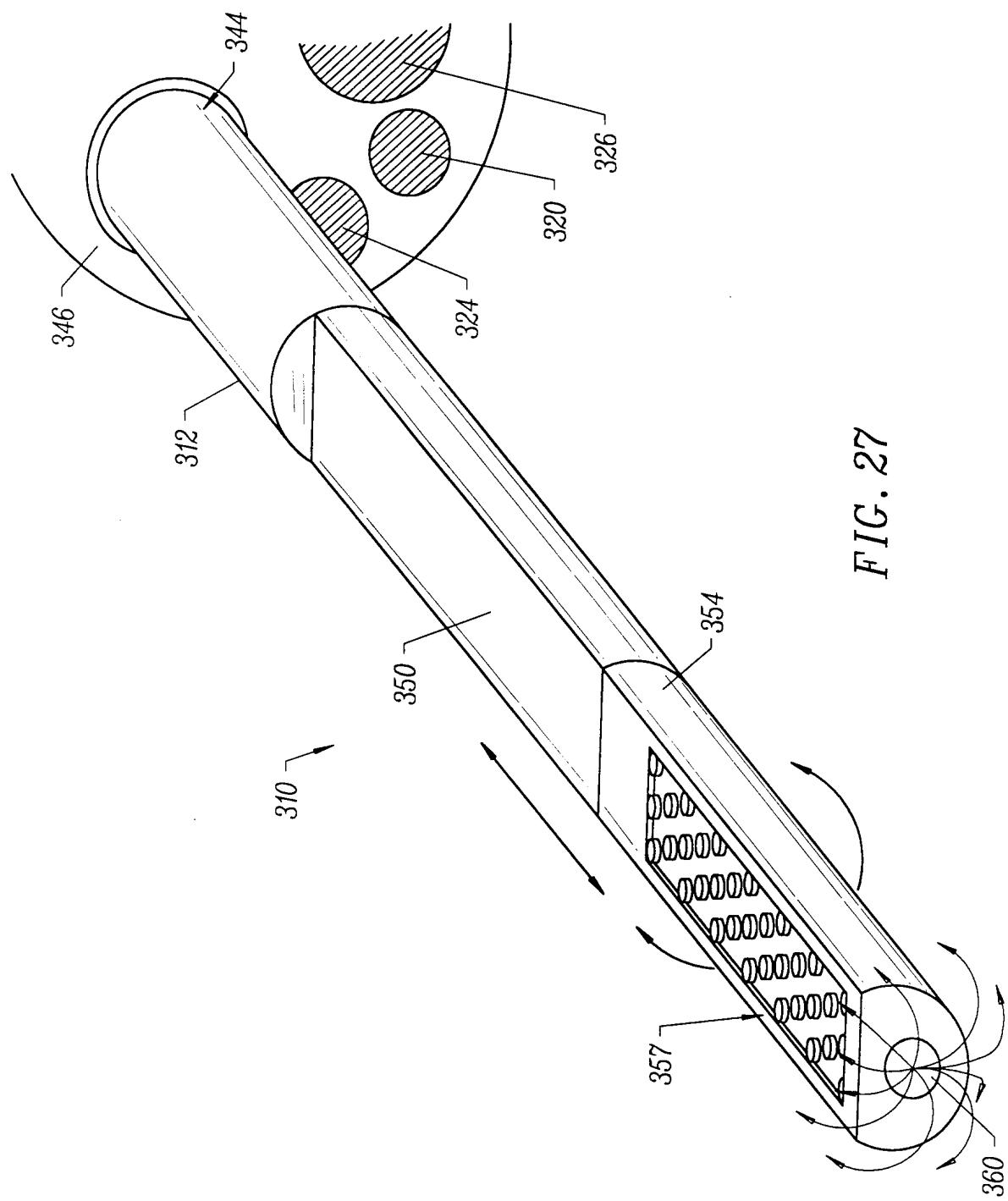


FIG. 26

31/54



32/54

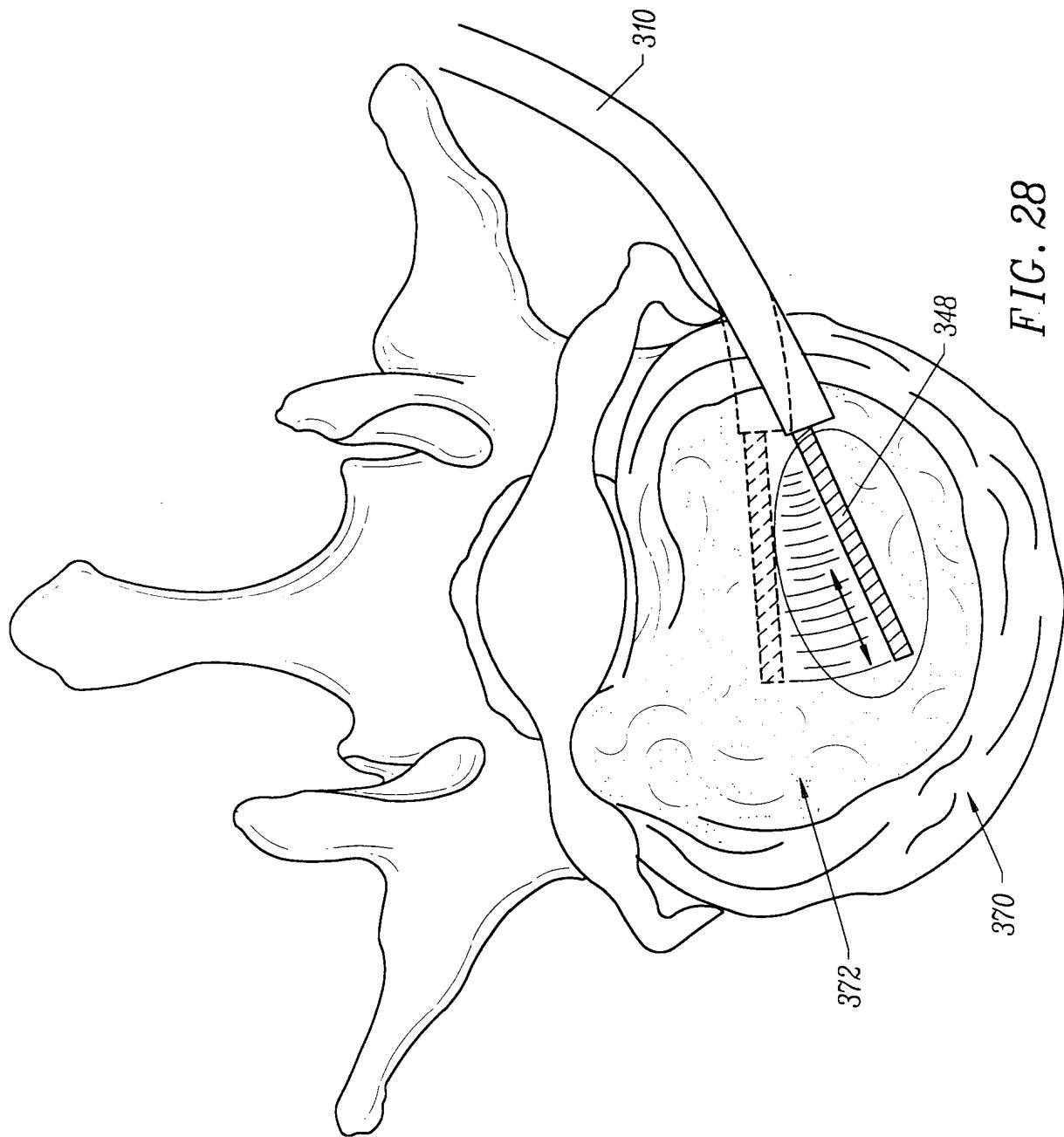


FIG. 28

33/54

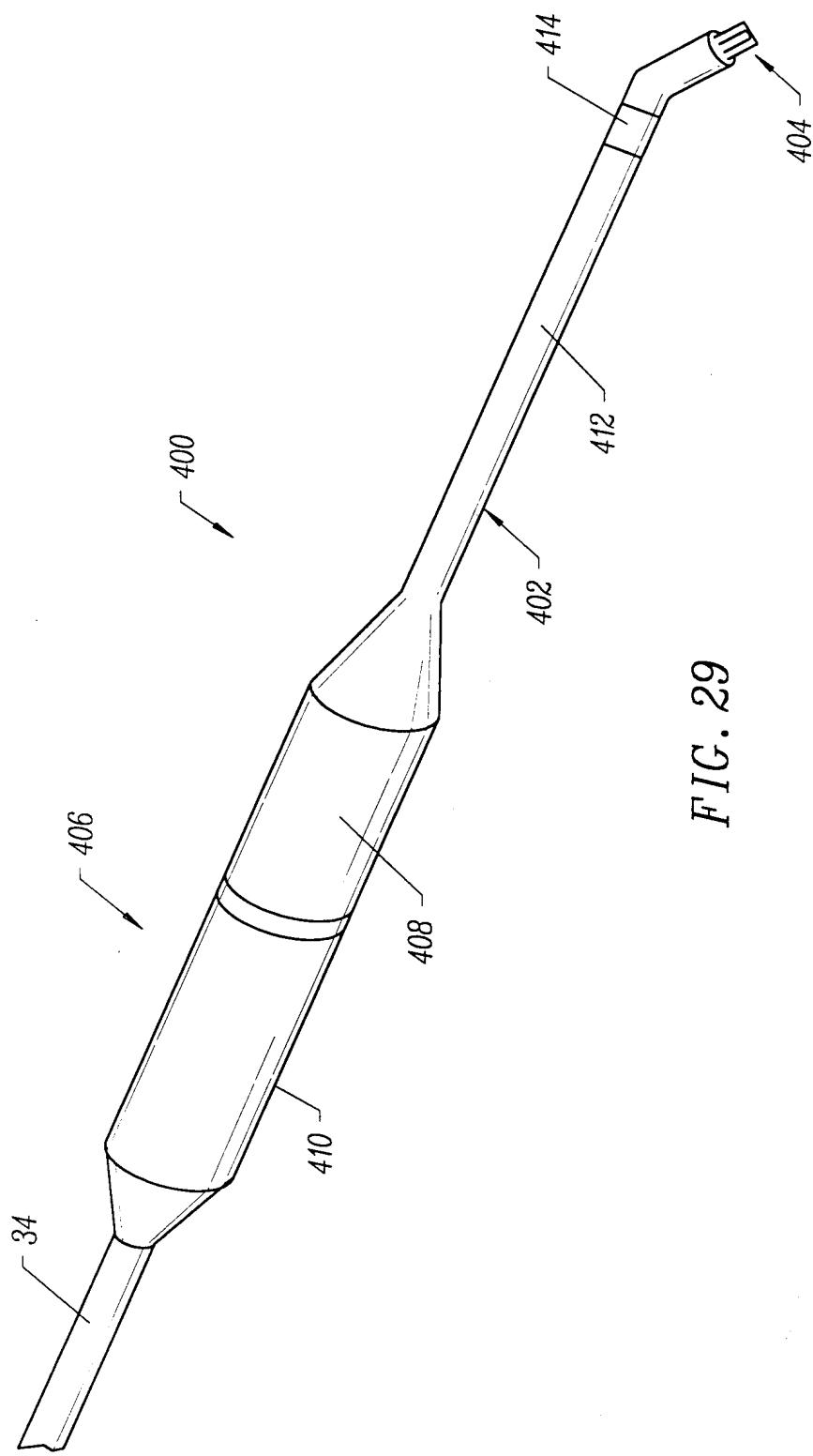


FIG. 29

34/54

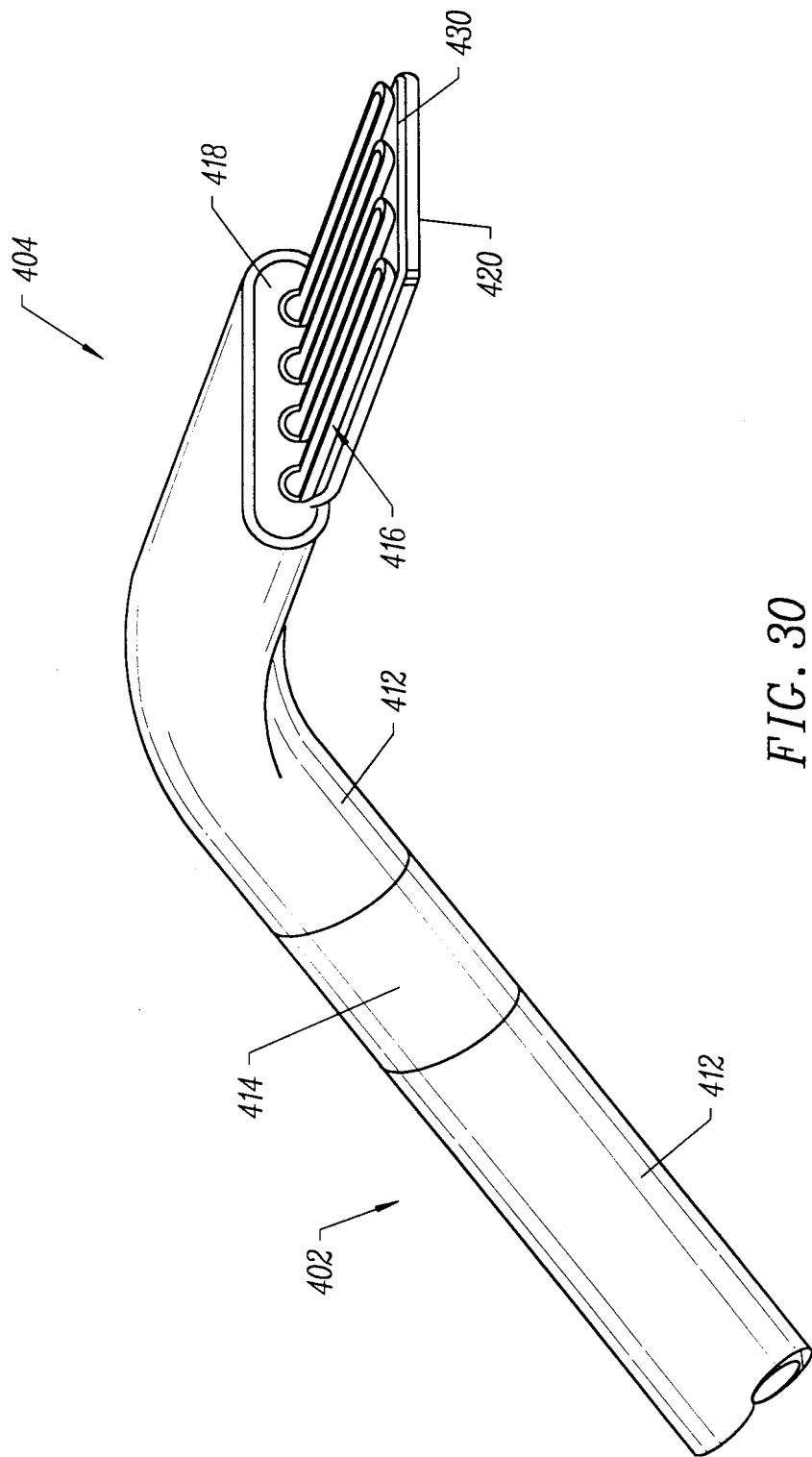


FIG. 30

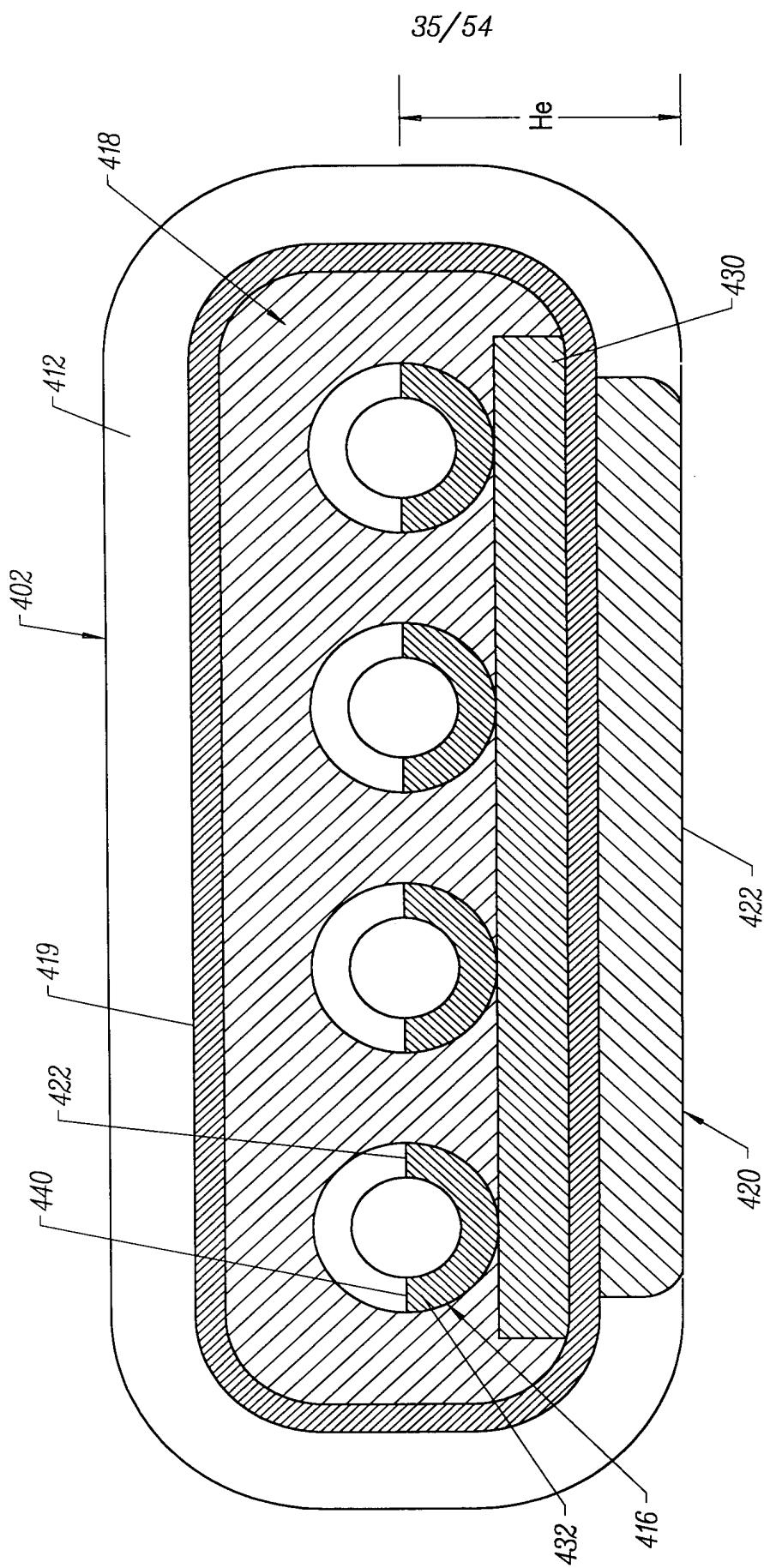


FIG. 31A

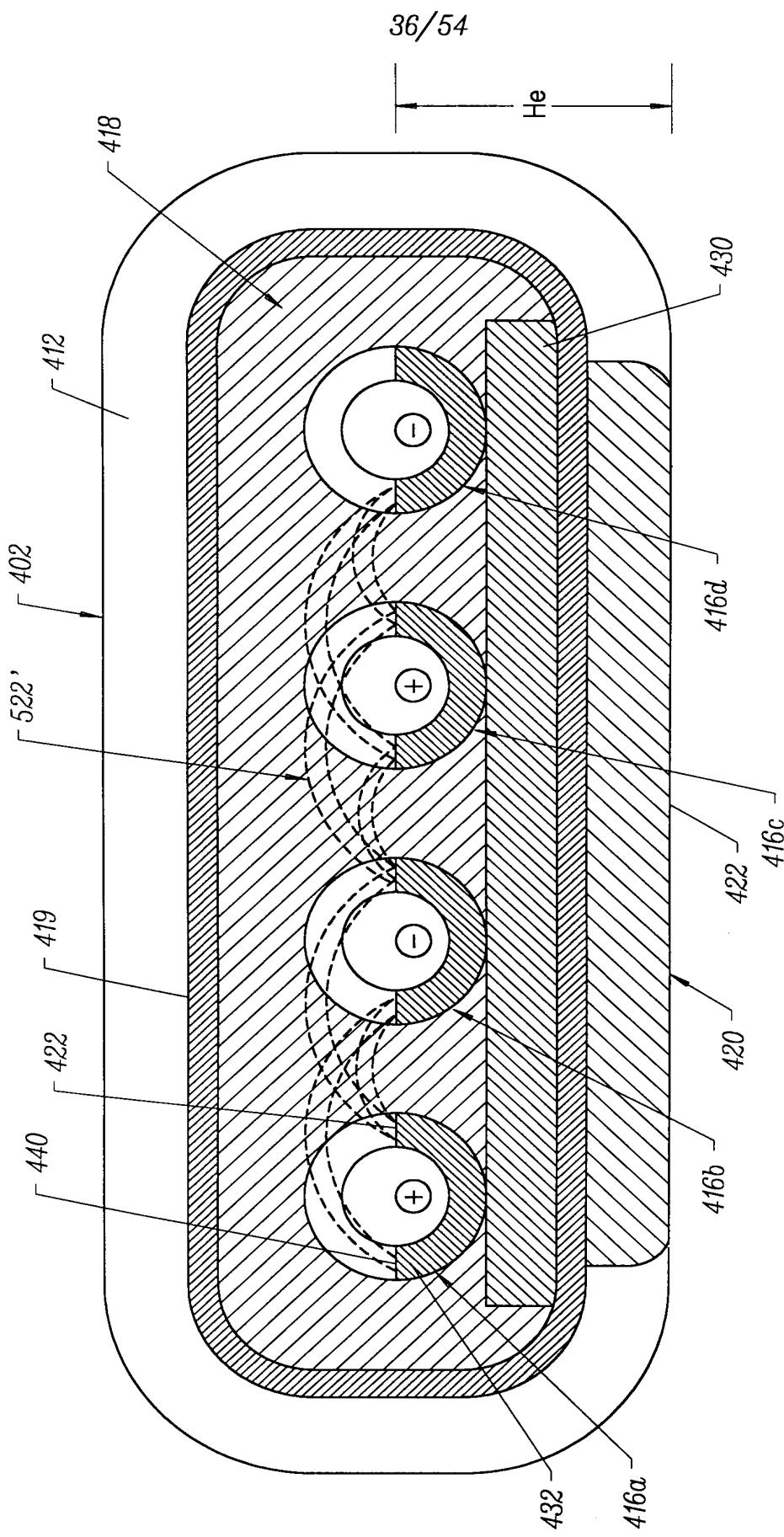


FIG. 31B

37/54

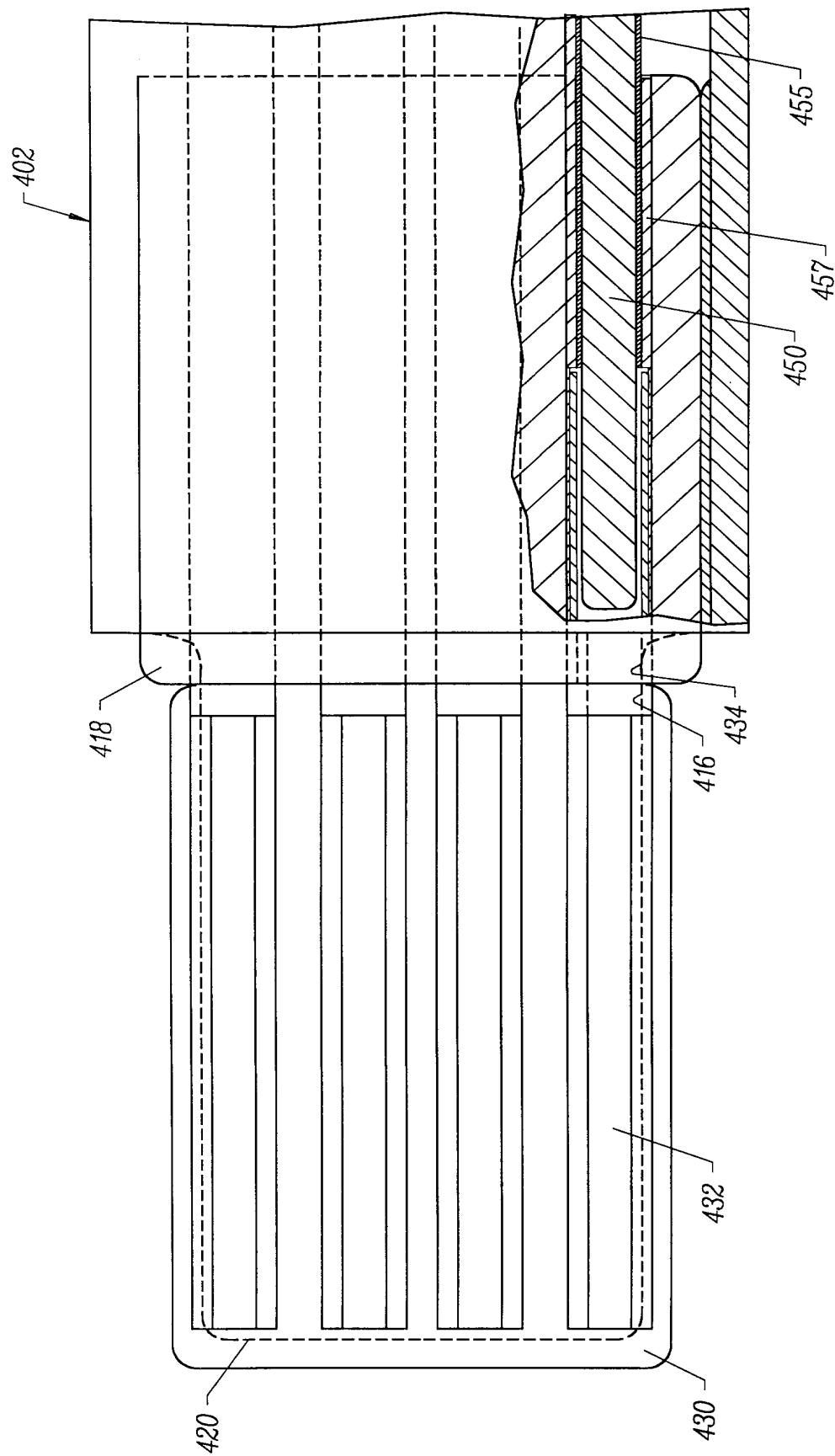


FIG. 32

38/54

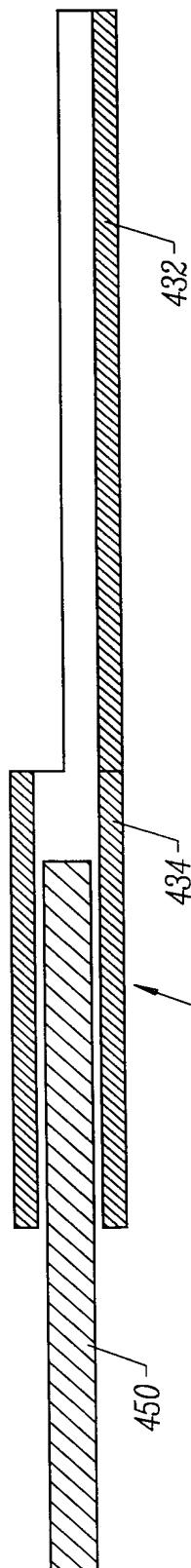


FIG. 33

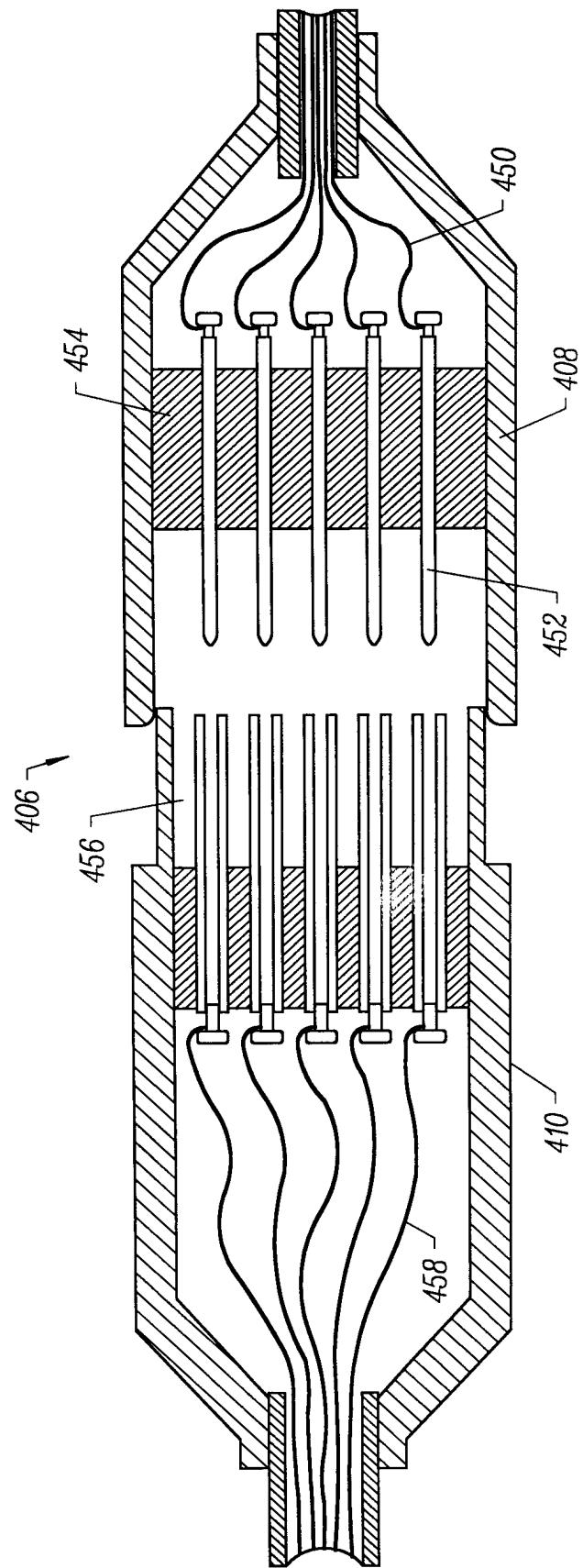


FIG. 34

39/54

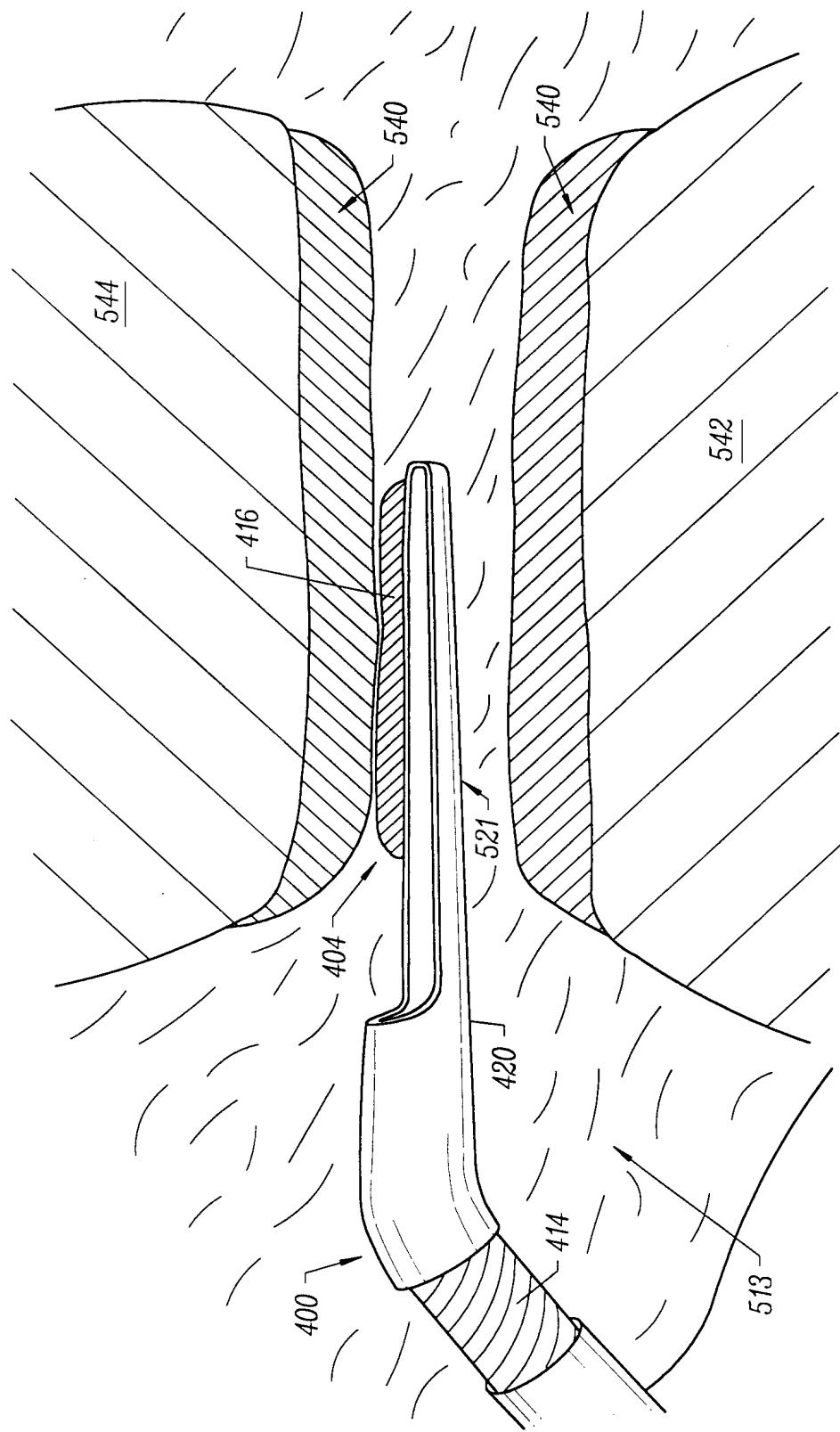


FIG. 35

40/54

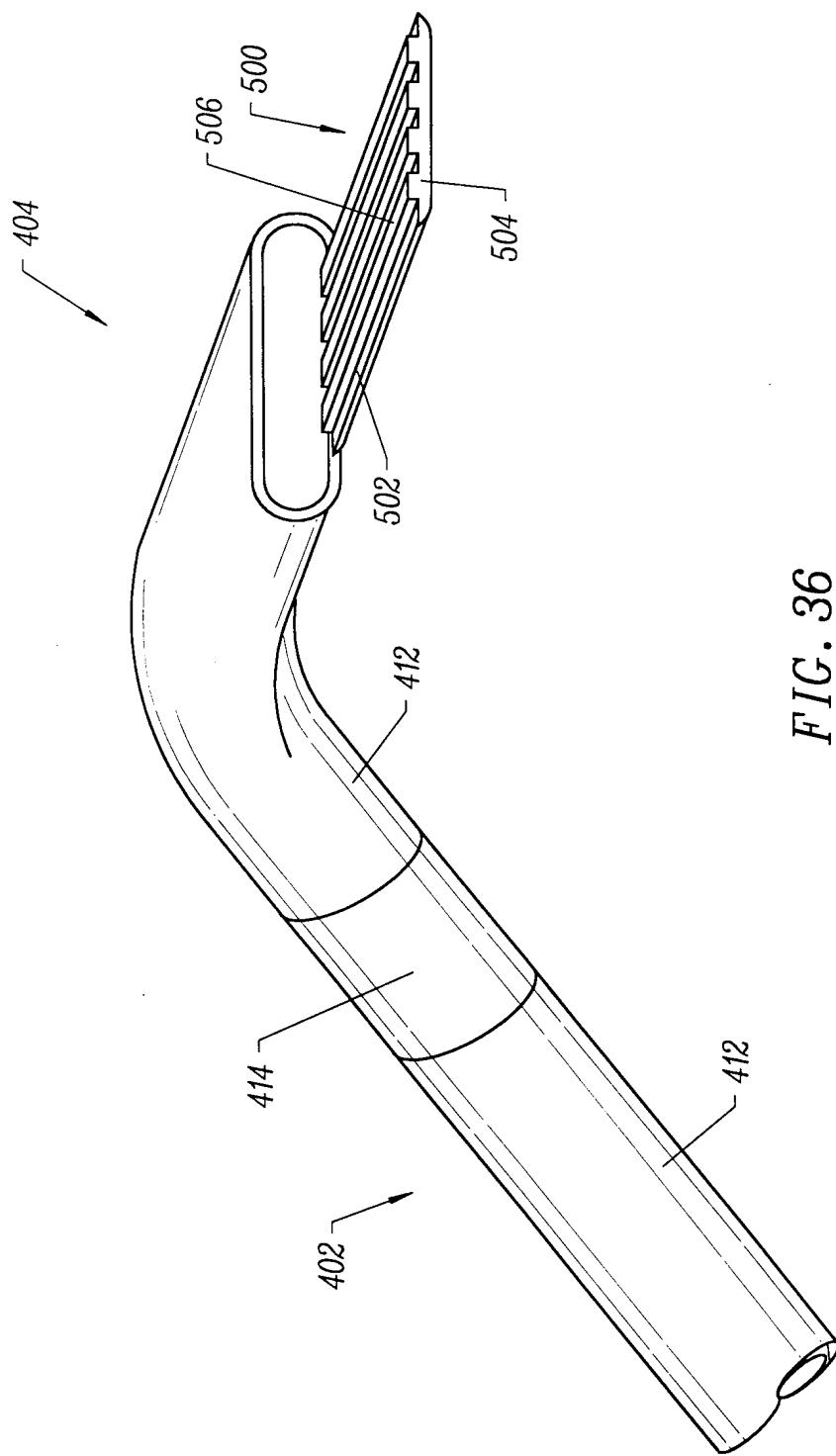


FIG. 36

41/54

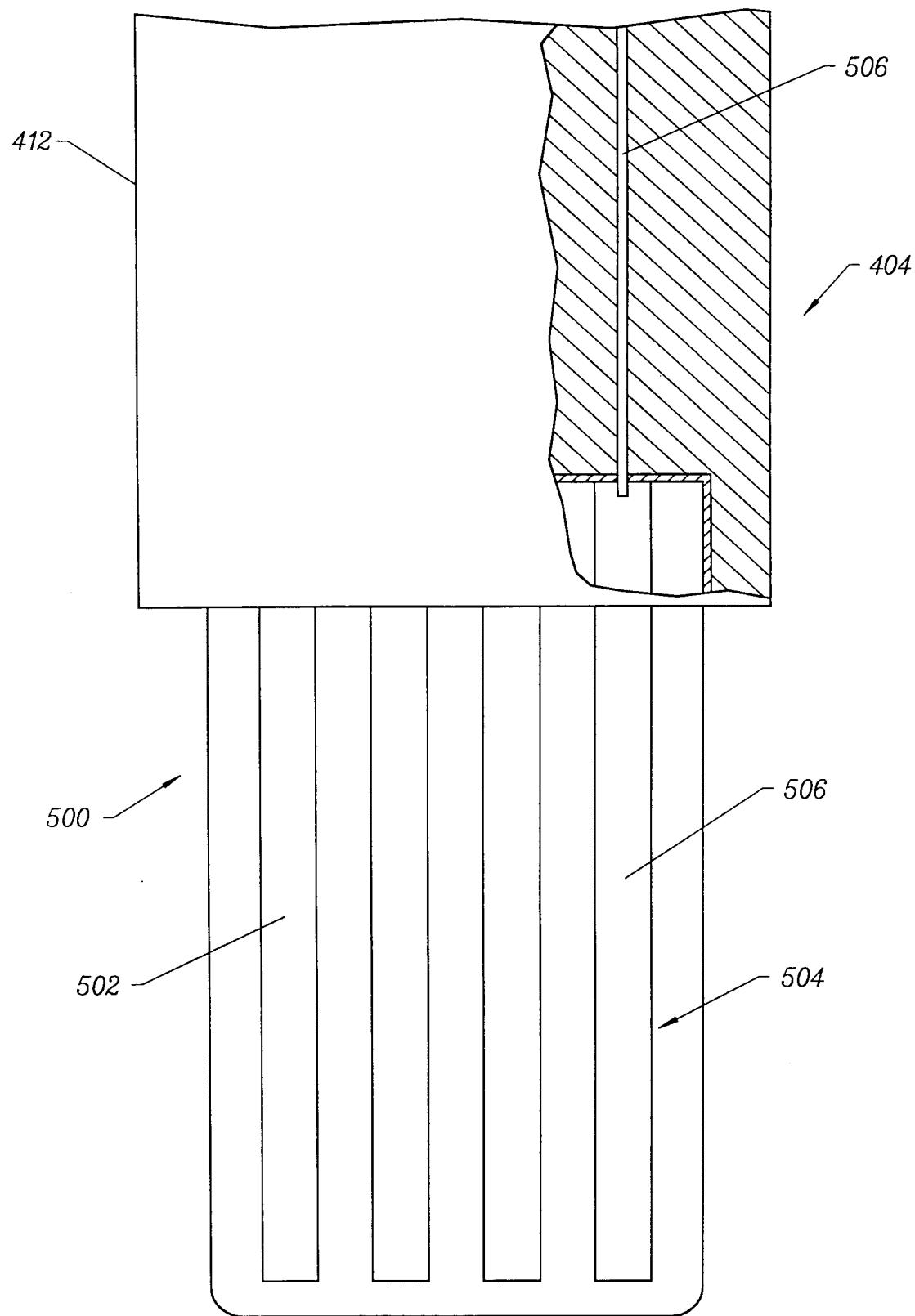


FIG. 37

42/54

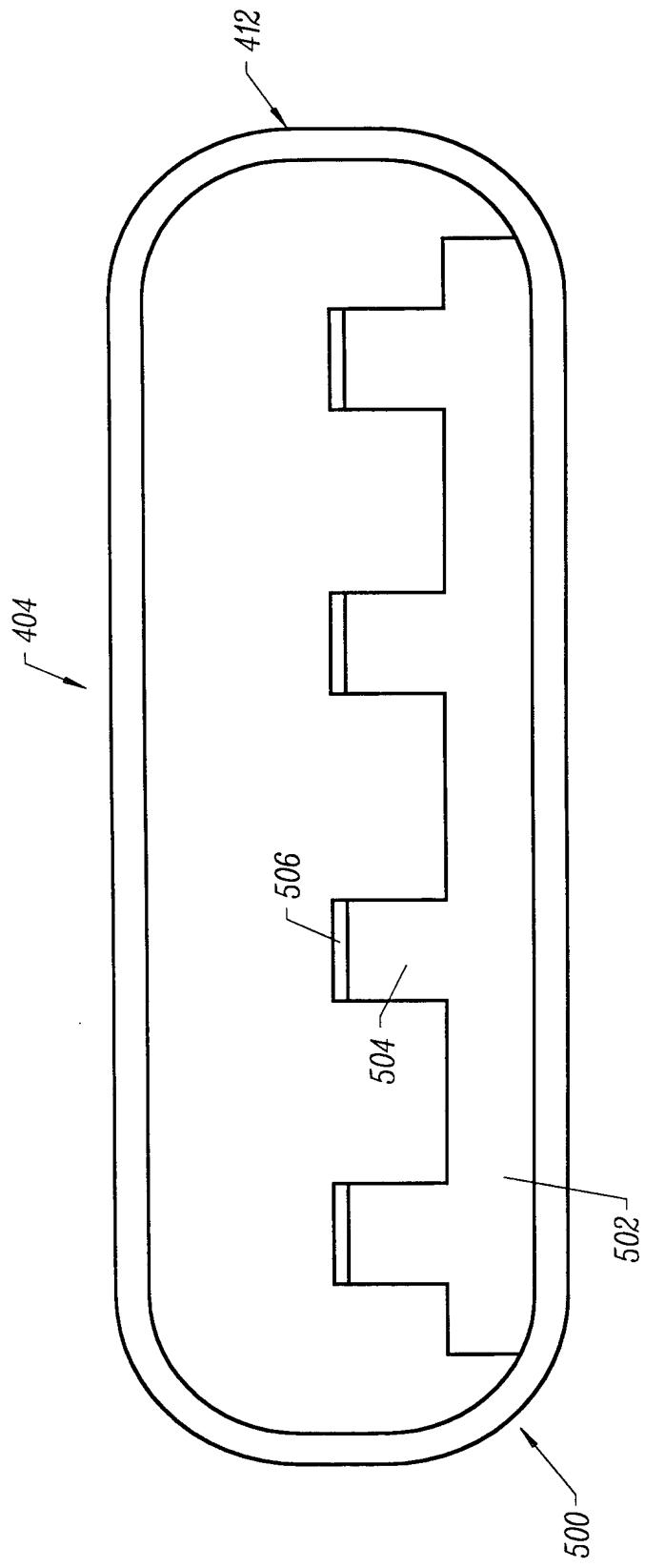
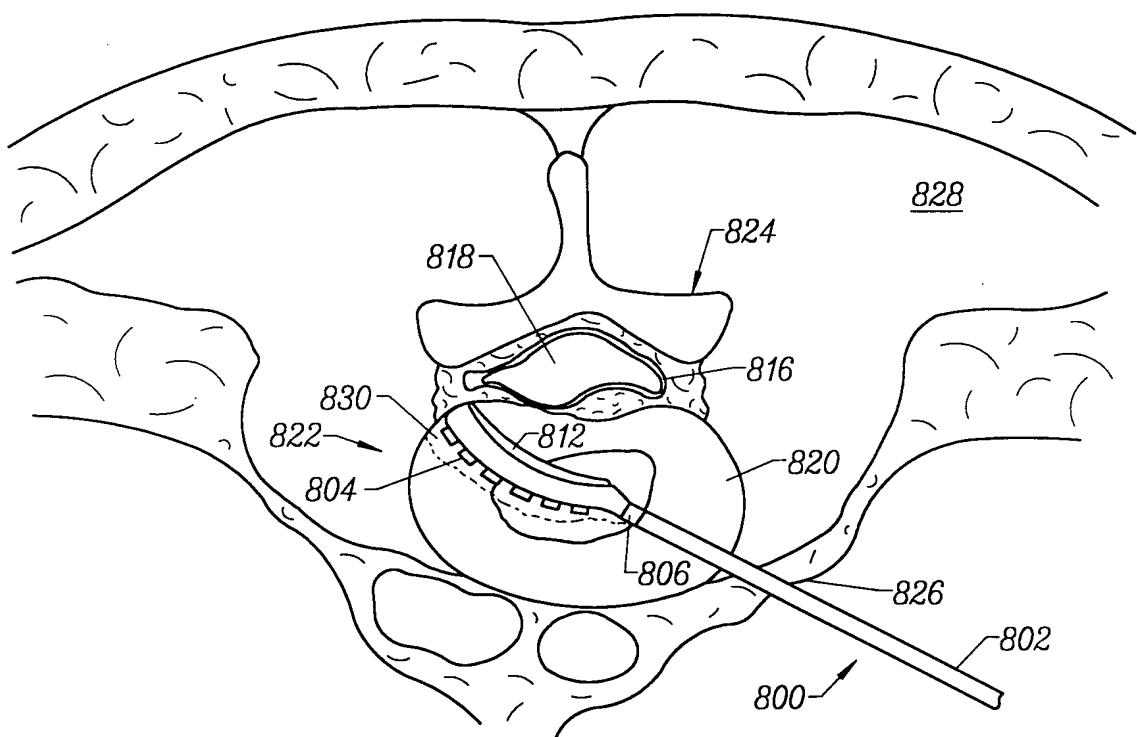
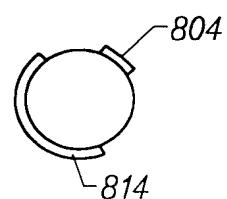
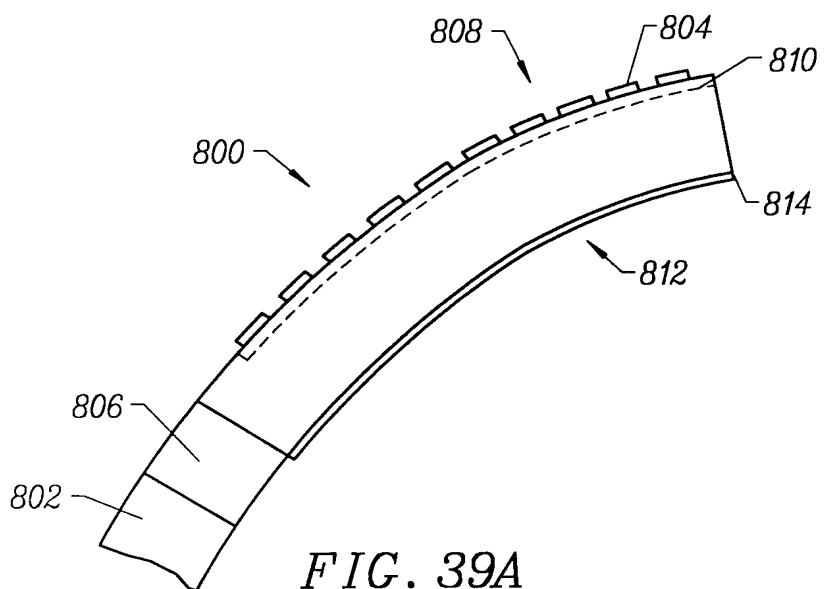


FIG. 38

43/54



44/54

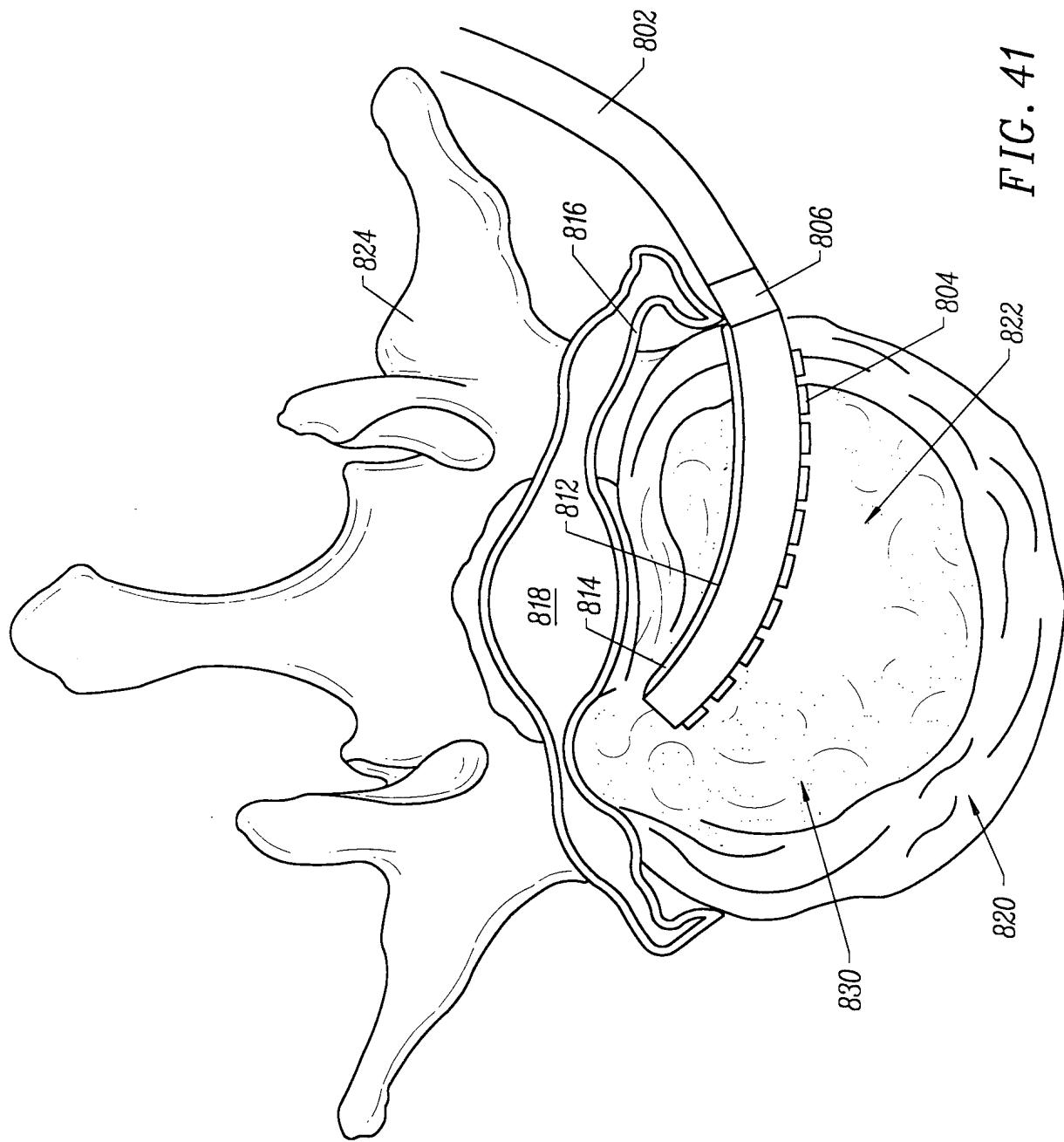


FIG. 41

45/54

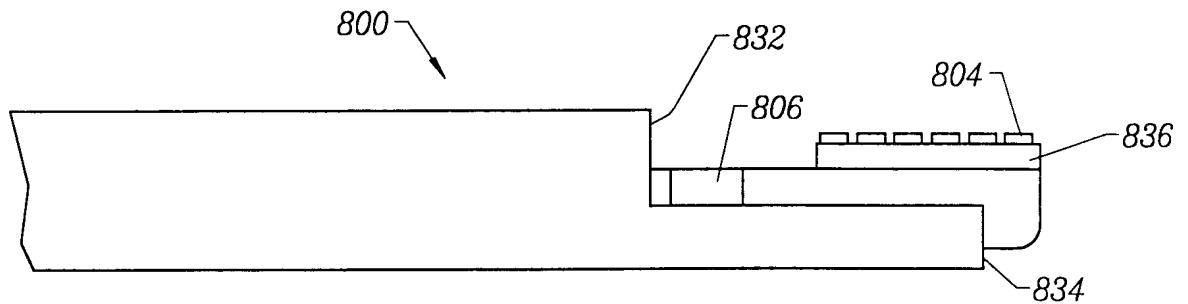


FIG. 42

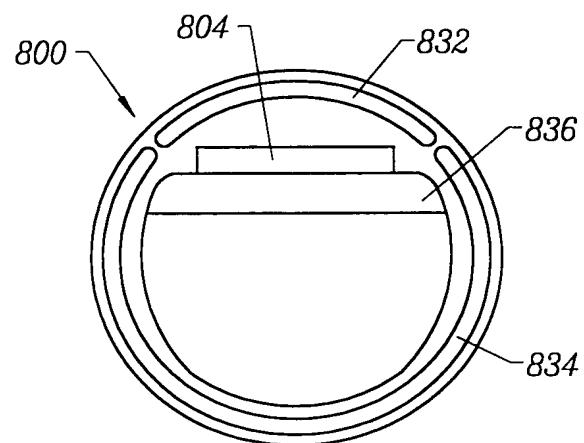


FIG. 43

46/54

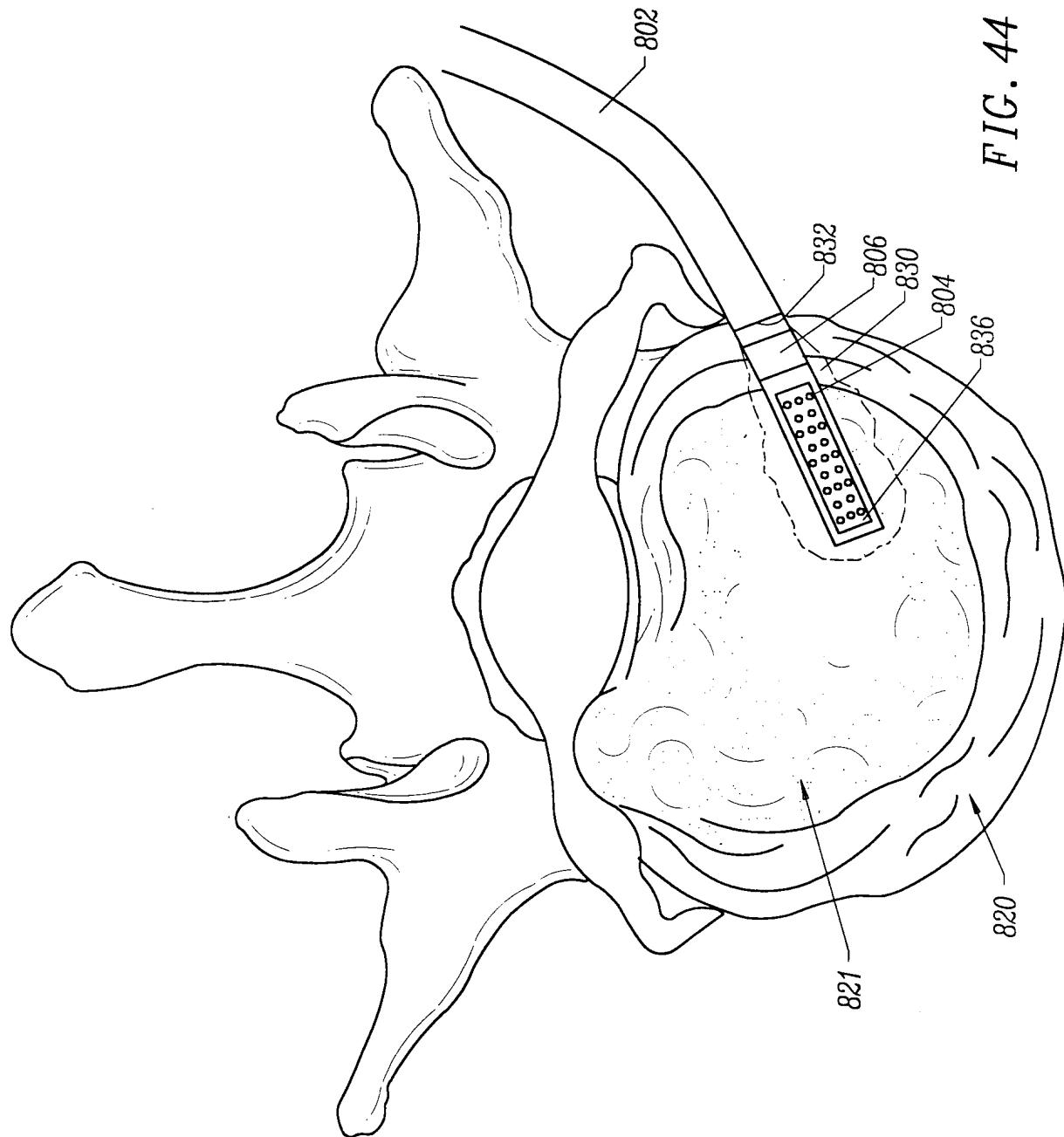


FIG. 44

47/54

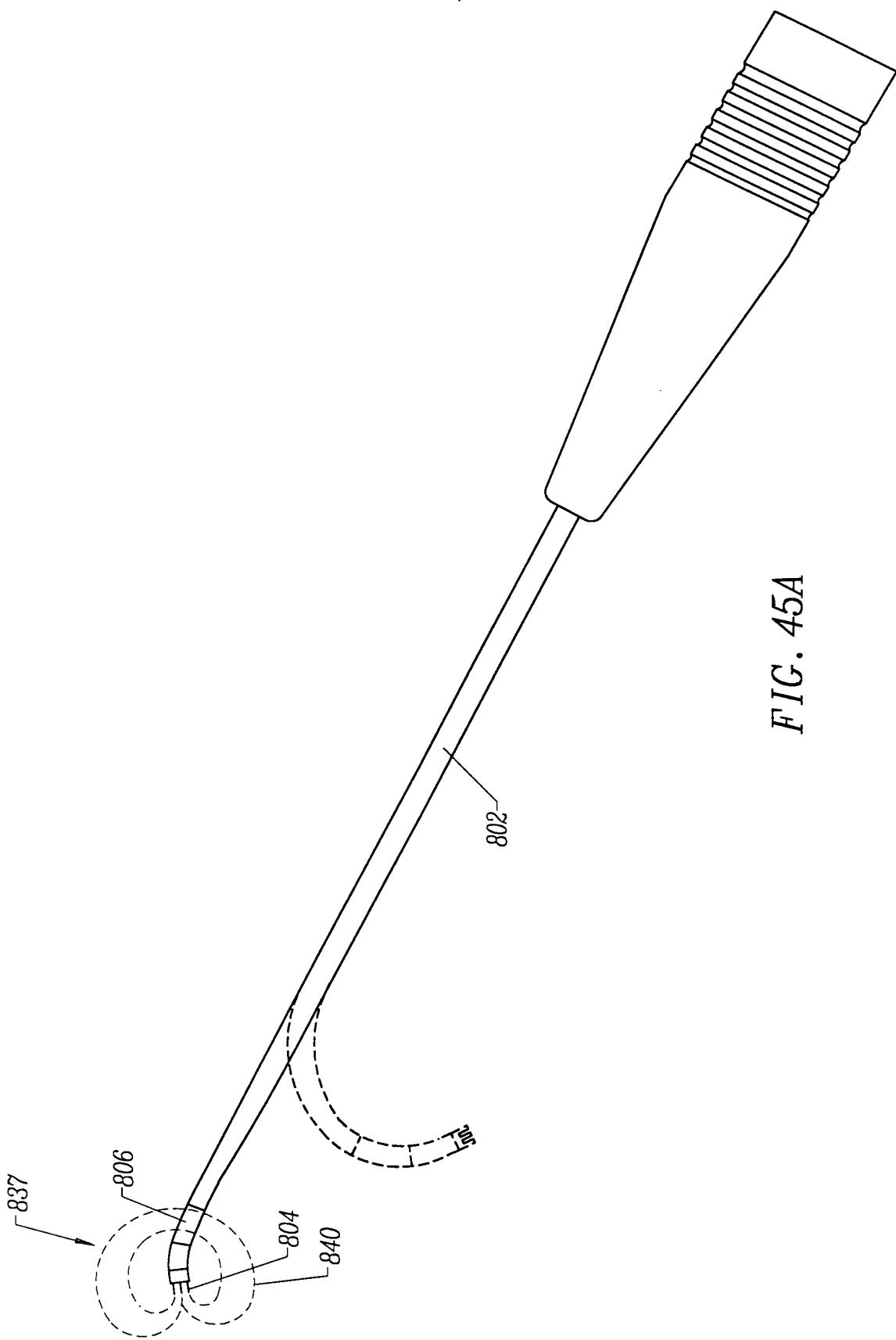


FIG. 45A

48/54

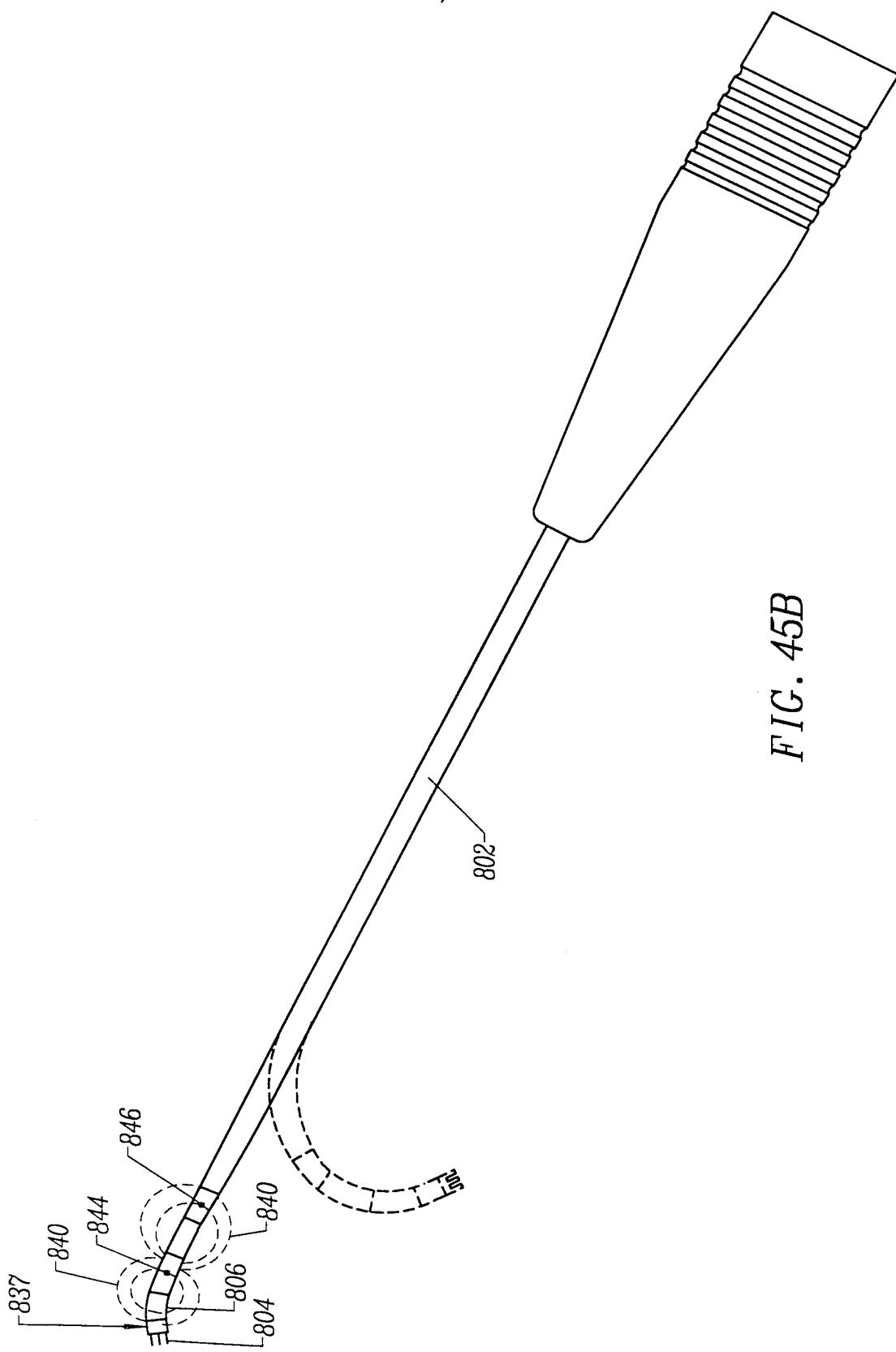
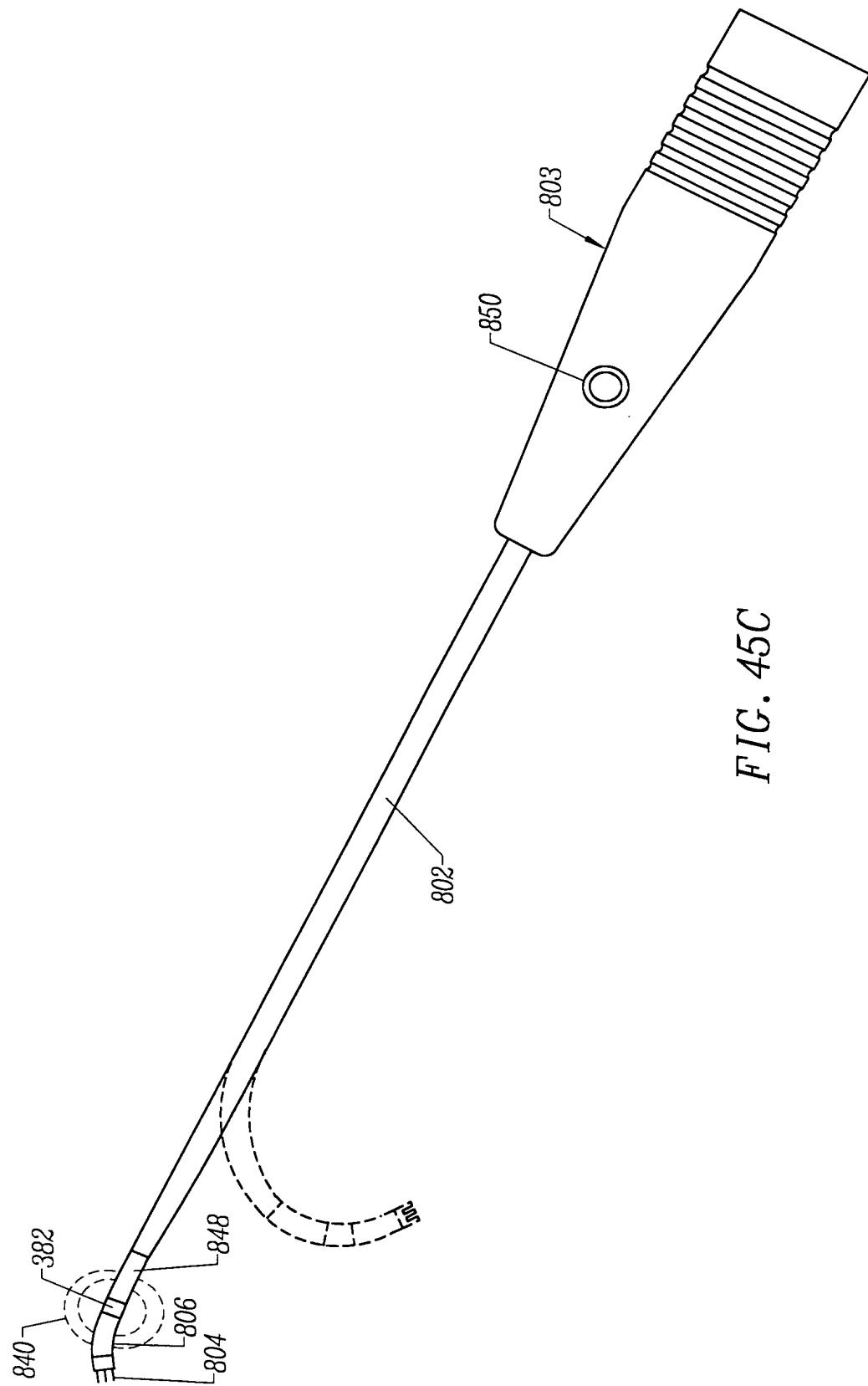


FIG. 45B

49/54



50/54

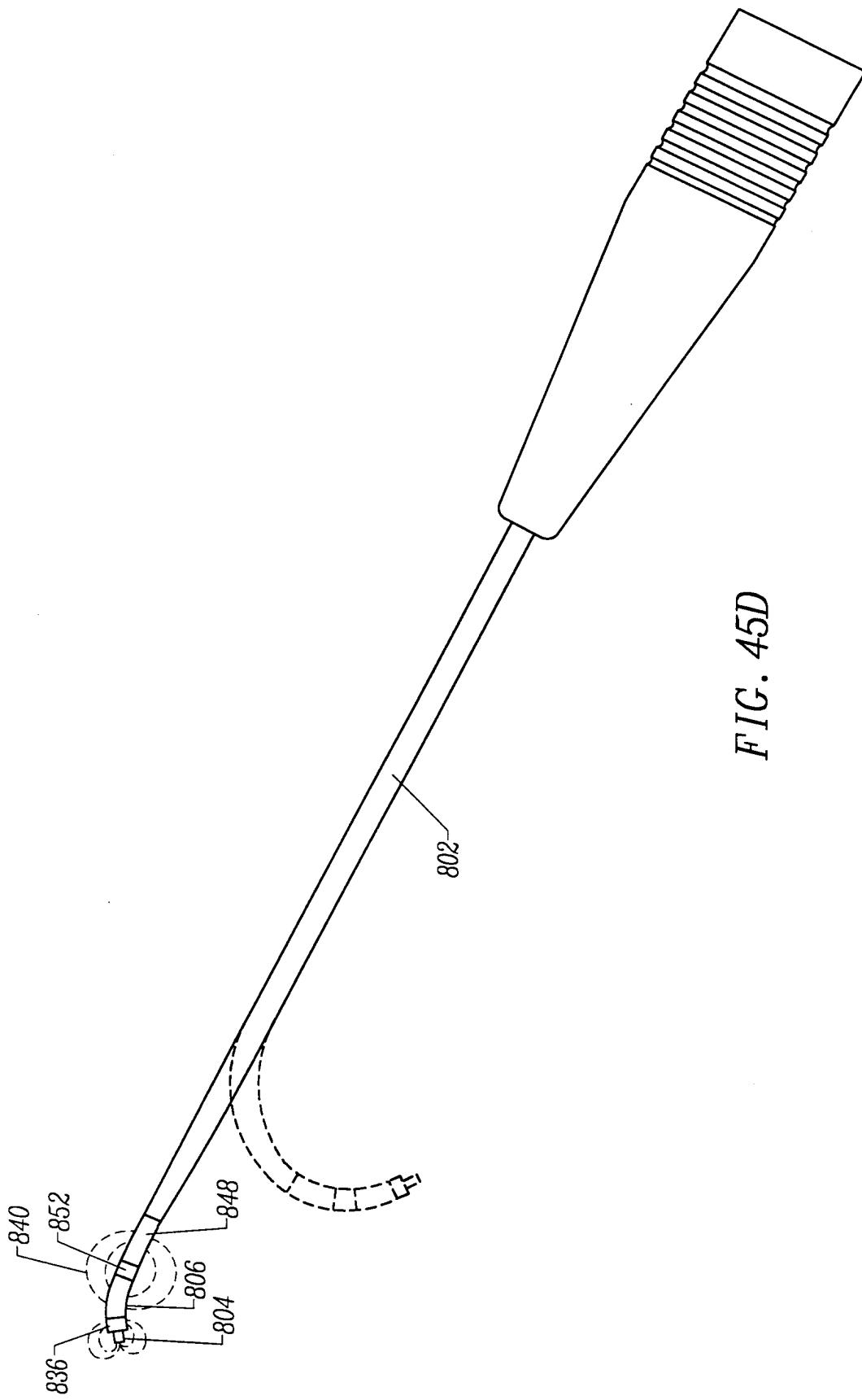


FIG. 45D

51/54

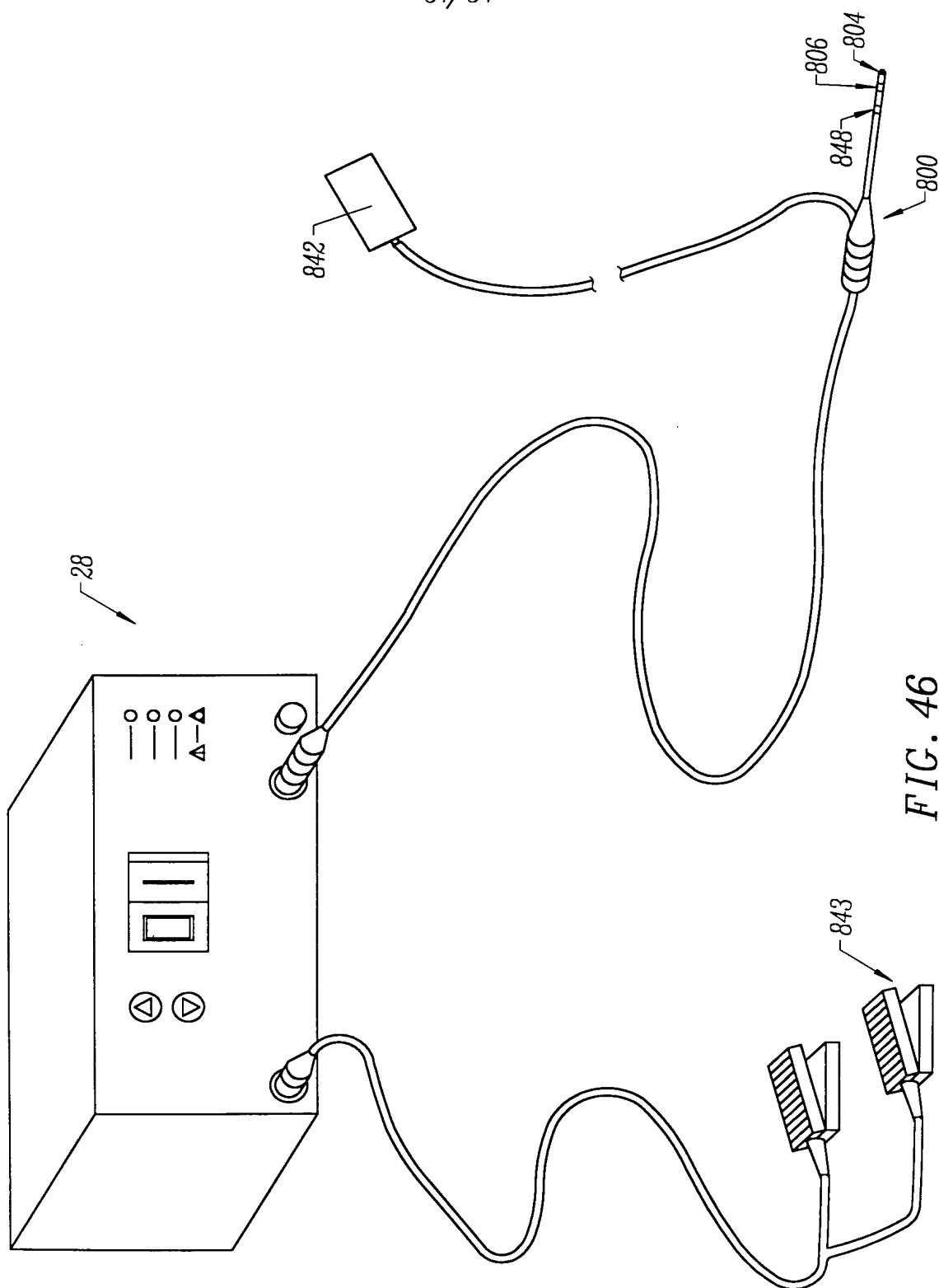


FIG. 46

52/54

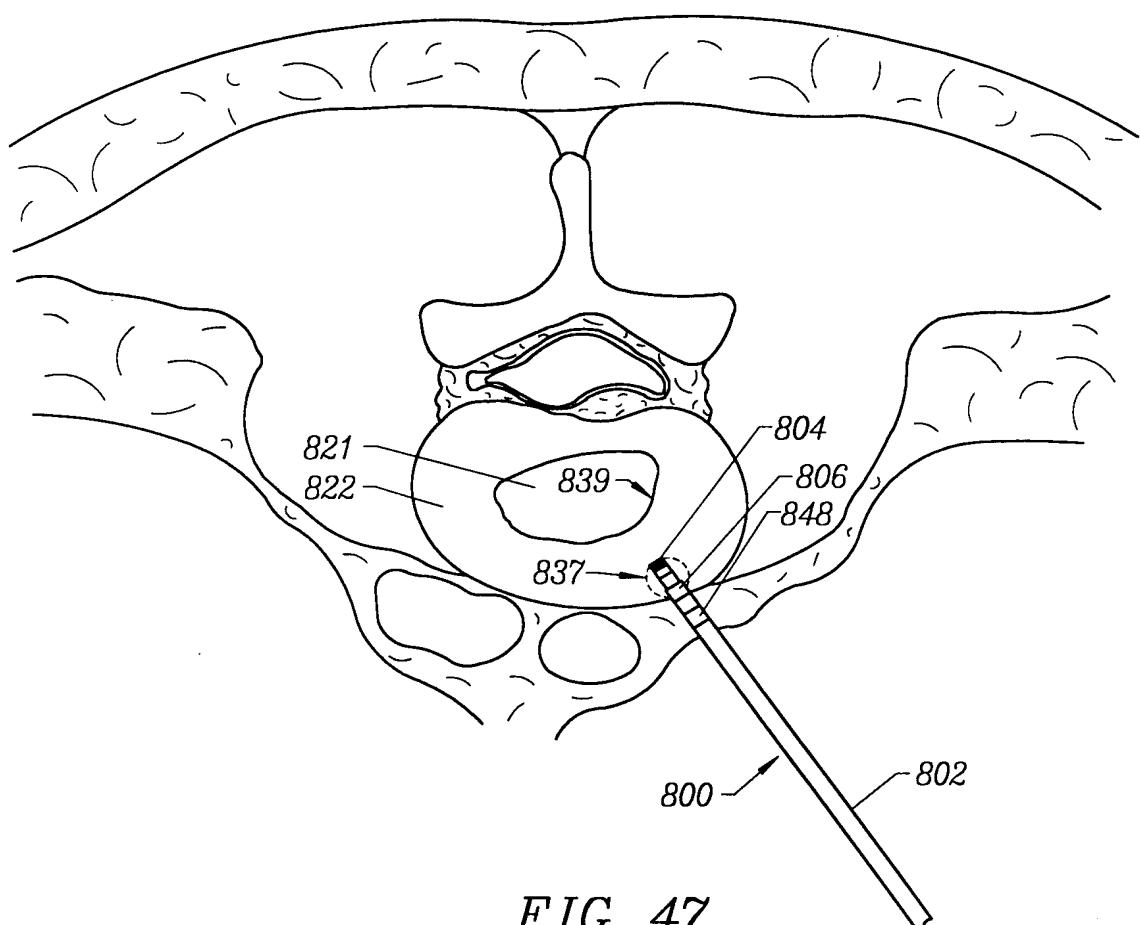


FIG. 47

53/54

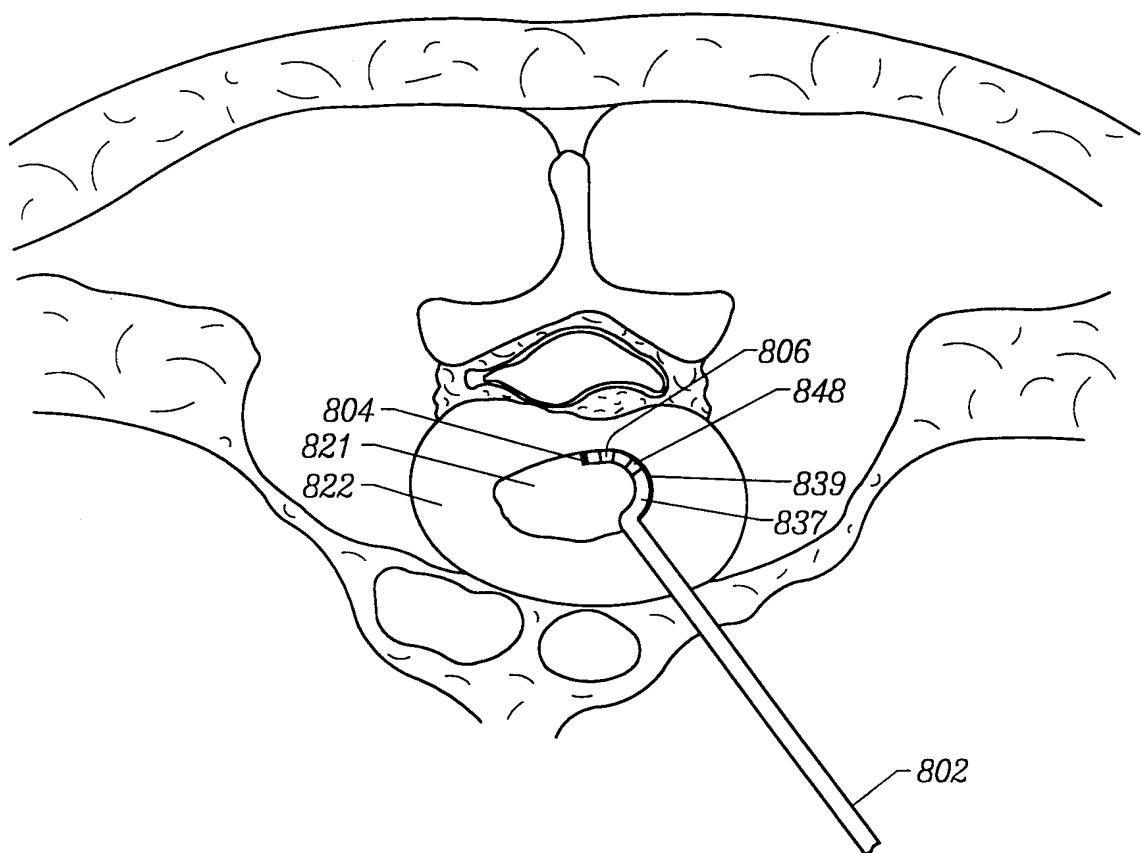


FIG. 48A

54/54

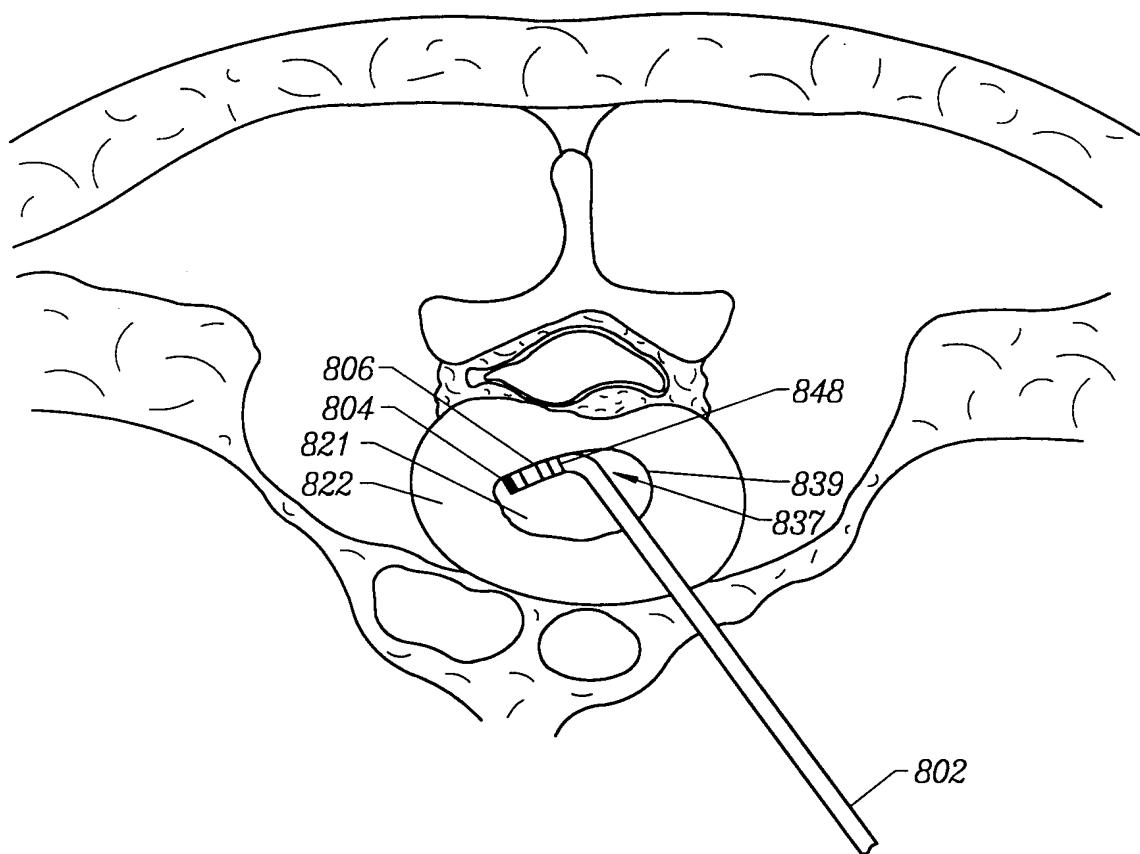


FIG. 48B

INTERNATIONAL SEARCH REPORT

International application No. PCT/US00/13706

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 18/14

US CL :604/22; 606/41, 45, 46, 48-50; 607/99, 105, 113; 604/22

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/41, 45, 46, 48, 49, 50; 607/99, 105, 113; 604/22

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,433,739 A (SLUIJTER et al.) 18 July 1995, entire document.	1-57
X	US 5,569,242 A (LAX et al.) 29 October 1996, entire document.	18, 19, 21, 41, 42, 44, 45, 48, 49
X	US 5,785,705 A (BAKER) 28 July 1998, entire document.	18, 19, 21-24, 36, 38, 39, 41, 42, 44-49, 53-55
X,P	US 6,013,076 A (GOBLE et al.) 11 January 2000, entire document.	18, 19, 21-24, 38, 39, 50-52

 Further documents are listed in the continuation of Box C. See patent family annex.

* Special categories of cited documents:

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"A" document defining the general state of the art which is not considered to be of particular relevance

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"E" earlier document published on or after the international filing date

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"&" document member of the same patent family

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search

Date of mailing of the international search report

27 JUNE 2000

31 JUL 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Authorized officer

LEE S. COHEN

Facsimile No. (703) 305-3230

Telephone No. (703) 308-2998